GEORGIA INSTITUTE OF TECHNOLOGY — OFFICE OF CONTRACT ADMINISTRATION

PROJECT ADMINISTRATION DATA SHEET

[x] ORIGINAL [ ] REVISION NO. _____

Project No. A-3328 DATE 9/2/82

Project Director: E.C. Burdette School/Lab ECSL/BRD

Sponsor: Intermedics, Inc.

Type Agreement: ~~Research Project Agreement No. A-3328~~ Purchase Order No. 50203

Award Period: From 8/12/82 To 10/31/82 (Performance) 10/31/82 (Reports)

Sponsor Amount: $11,021 ($5,000 advance payment) Contracted through:

Cost Sharing: GTRI/~~GIT~~

Title: Phase I Design Evaluation of a Prototype Medical Electromagnetic Hyperthermia System

ADMINISTRATIVE DATA

OCA Contact Faith G. Costello x4820

1) Sponsor Technical Contact:

Same as 2)

2) Sponsor Admin/Contractual Matters:

Mr. Reese Terry, Vice President
Corporate Technical Resources
Intermedics, Inc.
P.O. Box 617
Freeport, TX 77541

Defense Priority Rating: _____ Security Classification: _____

RESTRICTIONS

See Attached _____ Supplemental Information Sheet for Additional Requirements.

Travel: Foreign travel must have prior approval – Contact OCA in each case. Domestic travel requires sponsor approval where total will exceed greater of $500 or 125% of approved proposal budget category.

Equipment: Title vests with _____

COMMENTS:

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FORM OCA 4:781

GEORGIA INSTITUTE OF TECHNOLOGY OFFICE OF CONTRACT ADMINISTRATION

SPONSORED PROJECT TERMINATION SHEET

Date 12/15/82

Project Title: Phase I Design Evaluation of a Prototype Medical Electromagnetic Hyperthermia Syetem

Project No: A-3328

Project Director: E. C. Burdette

Sponsor: Intermedics, Inc.

Effective Termination Date: 10/31/82

Clearance of Accounting Charges: 10/31/82

Grant/Contract Closeout Actions Remaining:

- [x] Final Invoice and Closing Documents
- [ ] Final Fiscal Report
- [ ] Final Report of Inventions
- [ ] Govt. Property Inventory & Related Certificate
- [ ] Classified Material Certificate
- [ ] Other _____

Note to Accounting: Advance Payment of $5,000 to be applied against Final Invoice

Assigned to: ECSL/BRD (School/Laboratory)

COPIES TO:

Administrative Coordinator	Research Security Services	EES Public Relations (2)
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FORM OCA 10:781

A-3328

ENGINEERING EXPERIMENT STATION
GEORGIA INSTITUTE OF TECHNOLOGY • ATLANTA, GEORGIA 30332

October 13, 1982

Intermedics, Inc.
P. O. Box 617
Freeport, Texas 77541

Attention: Mr. Reese Terry, Vice President
Corporate Technical Resources

Reference: Intermedics Purchase Order No. 50203 and
GTRI/Intermedics Research Agreement, Project A-3328

Title: "Phase I Design Evaluation of a Prototype Medical Electromagnetic Hyperthermia System"

Contractor: Georgia Tech Research Institute

Subject: Monthly Progress Report No. 1 (8/12/82 - 8/31/82)
Georgia Tech Project A-3328

Principal Investigator: Everette C. Burdette (404) 894-3961

Dear Mr. Terry:

The overall objective of this program is to assess the performance and potential clinical suitability of an electromagnetic (EM) hyperthermia system based on "EMIT" technology developed by Spatial Dynamics, Ltd. (Baker, Oregon) for Intermedics, Inc. The present agreement is for a Phase I effort consisting of a technical system design review, theoretical performance appraisal, comparison to technical design approaches used in other EM hyperthermia systems, and identification of technical/operational problems which would affect the system's use in a clinical environment.

A summary of progress on the referenced research agreement for the period 12 August 1982 through 31 August 1982 is contained herein. During the first two weeks of this program, effort was concentrated on reviewing and assessing available information relevant to the design of the subject EM hyperthermia system. A brief summary of the work performed during this reporting period is presented below.

Work Accomplished

Using information provided by Intermedics and by Spatial Dynamics (design drawings, videotape, technical descriptions, etc.), an initial design review of the subject EM hyperthermia system was performed. Although significant descriptive information and specifics regarding expected system performance were provided, almost no information concerning the theoretical basis for the application design was available. After reviewing that information which was provided, the following questions were formulated:

1. What was the design basis for the "Bidirectionally Focusing Antenna"? (The descriptive information in the patent is useful, but nowhere is there a discussion of why and how the antenna is supposed to perform as claimed.)

2. Does the lens actually focus energy into a planar slab phantom model? If so, how is this accomplished? (This is not evident from the information provided.)

3. What are the spatial locations of the half-power (3 dB) points at $\lambda/8$ and $\lambda/4$ from the lens aperture (in a K=11 medium) as compared to the half-power points in the aperture?

4. Assuming that a "focusing effect" is achieved in a planar slab phantom, what effect does the presence of an irregular geometry (such as a breast) have on the "focused" pattern?

5. (a) How is impedance matching between the source and antenna acomplished?

   (b) Is there a means by which impedance matching can be adjusted to account for patient-to-patient variations, for changes due to temperature rise, and for effect of patient movement?

6. Does the second "port" on the "lens" actually mirror image the effects at the opposing port?

7. Is this device to be used only on breast tumors?

8. How are tumor heating and treatment temperature controlled?

9. Are thermistors out of the EM field? If not, how is their perturbation of the EM field taken into account?

10. (a) Are "air gaps" going to be present between the antenna and the tissue to be heated (e.g. breast tumor)?

    (b) If a gap is present, what method will be used to minimize stray radiation?

11. Does the tissue penetration depth of the EM field applied by this system differ significantly from the depth of penetration of an incident plane wave?

12. What shielding is provided for the system electronics? In particular, how is the power output control feedback loop protected?

13. Is it feasible to monitor heart rate and respiration (using EKG electrodes) with a high-intensity EM field present?

14. What is the function of the pump?

15. Are there plans for surface cooling of normal tissue directly beneath the lens?

16. Under what circumstances do the alarms sound?

17. What does the X-Y lens controller do?

In order to perform a useful and accurate assessment of the operation of the subject EM hyperthermia system and its potential for clinical use, it will be necessary to answer as many of the above questions as possible. To that end, a trip to Baker, Oregon during September 7-9, 1982 is planned for the purpose of testing the prototype system developed by Spatial Dynamics for Intermedics, Inc. . During that visit, it is planned to observe operation of the system, to attempt to obtain answers to the above listed questions, and to acquire useful additional technical information concerning the design basis of the lens antenna.

Plans For Next Reporting Period

During the next reporting period (September 1982), efforts will concentrate on establishing just how the "lens" works and assessing potential advantages and disadvantages of that approach with respect to other approaches presently being used or investigated. To gain greater insight into the system's operation, we will visit Spatial Dynamics in Baker, Oregon for acceptance testing of the prototype system. Additionally, the equipment configuration will be examined with regard for its future clinical use, and technical/operational problems that would significantly limit the system's use or effectiveness in a clinical environment will be identified. Subsequent to this trip, a theoretical assessment of the approach will be performed and overall suitability of the approach evaluated.

Respectfully submitted,

Everette C. Burdette
Project Director

APPROVED:

J. C. Toler, Chief
Biomedical Research Division

A-3328

ENGINEERING EXPERIMENT STATION
GEORGIA INSTITUTE OF TECHNOLOGY • ATLANTA, GEORGIA 30332

October 13, 1982

Intermedics, Inc.
P. O. Box 617
Freeport, Texas 77541

Attention: Mr. Reese Terry, Vice President
Corporate Technical Resources

Reference: Intermedics Purchase Order No. 50203 and
GTRI/Intermedics Research Agreement, Project A-3328

Title: "Phase I Design Evaluation of a Prototype Medical Electromagnetic Hyperthermia System"

Contractor: Georgia Tech Research Institute

Subject: Monthly Progress Report No. 2 (9/1/82-9/30/82)
Georgia Tech Project A-3328

Principal Investigator: Everette C. Burdette (404) 894-3964

Dear Mr. Terry,

The overall objective of this program is to assess the performance and potential clinical suitability of an electromagnetic (EM) hyperthermia system based on "EMIT" technology developed by Spatial Dynamics, Ltd. (Baker, Oregon) for Intermedics, Inc. The specific objectives of the present agreement for a Phase I design review effort were listed in Monthly Progress Report No. 1.

A summary of progress on the referenced research agreement for the period 1 September 1982 through 30 September 1982 is contained herein. During this period a trip to the offices/laboratories of Spatial Dynamics, Ltd. was make by Intermedics and Georgia Tech personnel. Based on the information learned on that trip through discussions with Mr. Tex Yukl of Spatial Dynamics and through observation of equipment operation, a first-order theoretical assessment of the antenna design approach was performed and specific needed system design improvements were identified. A summary of the work performed during this reporting period is presented in the following paragraphs.

Work Accomplished

The focus of the work performed during September 1982 was the visit to Spatial Dynamics, Ltd. for a demonstration and acceptance testing of the EM hyperthermia system developed for Intermedics, Inc. A trip report describing our observations and findings during that visit is attached (Attachment 1). In that report, several modifications to the system are recommended, particularly with respect to control and alarm functions.

Subsequent to discussions with Tex Yukl of Spatial Dynamics, an examination of the "EMIT" technology was performed to gain insight into what is theoretically possible with respect to energy concentration away from the antenna aperture. First, it is well known that focusing in the ray optics sense does not occur unless the focusing device is minimally several wavelengths across and several wavelengths thick [1]. In the system developed by Mr. T. Yukl of Spatial Dynamics, the lens design does not meet the physical criteria necessary for focusing in the ray optics sense. Therefore, if energy concentration beyond either aperture of the bidirectional antenna does take place, it must be accomplished by some other means. Assuming that a concentration of energy at or beyond the aperture exists, the smallest spatial extent, or "width", of the concentrated energy can be determined from the plane wave expansion of the emitted complex waveform.

Any complex waveform can be expressed as the sum of different plane waves with different amplitudes and phases, and even different directions of propagation [2]. Thus, for any given direction, the resulting wave function is a vector summation of the various plane-wave components. Upon performing this operation, one observes that in a given direction for a single frequency, the propagating wave will be sinusoidal with a period fixed by the medium and the frequency. Thus, the half-power points will be spaced 90 degrees, or one quarter wavelength, apart. In air, at 333 MHz, the half-power points would be spaced 22.5 cm apart. In a medium having a relative dielectric constant of 11, the half-power points would be 6.78 cm apart. The aperture of the prototype device examined was 22.5-cm in diameter. Thus, no power density concentration would be anticipated in air; however, the power density in a medium with a relative dielectric constant of 11 would increase by a factor of 10.9, or approximately 10 dB. This appears encouraging. However, note that the same "concentration" would occur for any applicator coupled directly (beginning at the aperture) to the same dielectric medium (K = 11). Note also that the above analysis is for the ideal case. Normal diffraction from an aperture results in a pattern in which adjacent maxima are one wavelength or more apart [3], so that generally energy concentration at an extent or "width" of less than a wavelength does not occur. In view of these brief theoretical considerations, the ability of the "Bidirectionally Focusing Antenna" to effectively concentrate energy more so than conventional dielectric-loaded applicators is doubtful.

The device (antenna) we examined appears to be a loop-excited, leaky cavity with some dielectric loading. The effect of the dielectric loading is unclear; however, it would appear to affect the effective electrical circumference of the excited and parasitic loops. The effect of the "director" loops (parasitic loops) is also somewhat unclear, although it is highly likely that the close spacing of the director loops may actually produce the narrowband cavity-like characteristics of the device. A "rough" set of measurements performed on the device during our visit at Spatial Dynamics suggests that the antenna has a high quality factor (Q=170) with the center frequency at 338 MHz. As a result of this high Q, small changes in the impedance match of the antenna to the tumor (or phantom) being heated may cause serious problems in coupling the desired power to the tumor.

From the information we gathered during the visit at Spatial Dynamics in Baker, Oregon, there is little evidence to suggest that any "focusing" of the emitted field from the bidirectional antenna is taking place. Clearly, no focusing in the geometrical optics sense can take place in a device of such small dimensions relative to the operational wavelength. Considering the device as a leaky cavity, fringing fields from the device may peak at some distance in a dielectric medium, but such an effect would be highly dependent upon the dielectric medium's geometry. Further, analysis of this effect would require the use of numerical techniques on a mainframe computer and the results would be different for each specific dielectric material and geometrical configuration.

Testing of the device in a relatively small volume of phantom media (in terms of skin depth) makes it likely for standing waves to be produced from reflections at air/media and media/air interfaces. Those standing waves would have half-power "points" one-quarter wavelength apart. The locations of standing wave maxima would change as a function of the depth (thickness) of the phantom media and could be mistaken as focusing of EM energy.

The most appropriate method to determine the field pattern emitted by the bidirectionally focusing antenna would be to systematically measure its radiated field pattern at various distances from the aperture. A recommended method for characterizing the radiated field pattern would be to measure the field intensity over a plane directly in front of the aperture and orthogonal to the antenna's axis. Measurement points in the plane should be spaced one quarter wavelength apart. Measurements should be performed at several distances from the aperture. These should minimally include measurements in or near the plane of the aperture itself and at distances of 1/4, 1/2, and 1 wavelength away from the aperture. Such measurements should be performed both in air and in a test dielectric medium (K=20 to K=30), both with and without the "opposite aperture" terminated in a dielectric phantom. Carefully performed measurements for the four cases stated above at the suggested distances from the aperture (which are referenced to a single maximum field intensity) should provide satisfactory information for assessing the true character of the emitted field pattern and whether or not any significant energy concentration takes place. Results from such measurements will be needed before a final recommendation concerning continued development of the present EM hyperthermia system is made.

PROBLEMS ENCOUNTERED

The primary problem encountered during this reporting period was testing of the hyperthermia system during our visit at the facilities of Spatial Dynamics. It was apparent that (1) the system was not yet ready for acceptance testing and (2) facilities and measurement equipment at Spatial Dynamics were not adequate for testing of the system to a degree consistent with its specifications. However, with two exceptions, those problems will not prohibit Georgia Tech personnel from appropriately evaluating the EM hypethermia system designed by Spatial Dynamics. The two exceptions which are of critical importance are (1) an accurate measurement of the efficiency of the system

for heating a lossy dielectric material and (2) adequate characterization of the field pattern at various distances from the antenna aperture in at least two media (such as described in the final paragraphs under Work Accomplished).

To optimally complete the performance assessment and evaluation of the subject EM hyperthermia system, the results of carefully-performed field pattern measurements are needed. These results may either be provided by Spatial Dynamics or obtained under the Phase II Georgia Tech efforts.

PLANS FOR NEXT REPORTING PERIOD

During the final month of the Phase I evaluation study, efforts will be directed toward completion of the following tasks:

1. completion of the performance assessment of the subject EM hyperthermia sysem;

2. comparison of techniques used in the subject system to other presently employed or developing technologies and their relative advantages/-disadvantages;

3. examination of the subject system with regard to its future clinical use;

4. identification of tasks to be performed during the Phase II testing and Phase III clinical evaluation efforts; and

5. preparation of the final technical report and presentation of the Phase I assessment results to Intermedics personnel.

Respectfully submitted,

Everette C. Burdette
Project Director

APPROVED:

J. C. Toler, Chief
Biomedical Research Division

REFERENCES

1. J. D. Krauss, "Lens and Long Wire Antennas", Ch. 14, 382-407 in ANTENNAS, McGraw-Hill, New York, 1950.

2. R. F. Harrington, FIELD COMPUTATION BY MOMENT METHODS, Macmillan, New York, 1968.

3. F. A. Jenkins and H. E. White, FUNDAMENTALS OF OPTICS, 232-241, McGraw-Hill, New York, 1957.

ATTACHMENT 1

REPORT OF TRIP TO SPATIAL DYNAMICS ON PROJECT A-3328

REFERENCE: Georgia Tech Project A-3328, "Phase I Design Evaluation of a Prototype Medical Electromagnetic Hyperthermia System"

AGENCY VISITED: Spatial Dynamics, Ltd.

LOCATION: Baker, Oregon

DATES: September 7-9, 1982

CONTACT: Mr. Tex Yukl

BY: E. C. Burdette and D. J. Schaefer

Under Project A-3328, E. C. Burdette and D. J. Schaefer of the Biomedical Research Division of Georgia Tech's EES accompanied Mr. Reese Terry, Vice President for Corporate Technical Resources at Intermedics, Inc. on a trip to Baker, Oregon to meet with Mr. Tex Yukl of Spatial Dynamics, Ltd. The primary purpose of this visit was to perform acceptance tests of the prototype EM hyperthermia system developed by Spatial Dynamics for Intermedics. Meetings/-discussions with T. Yukl were also held for the purpose of answering questions posed in Monthly Progress Report No. 1. On the final day of the trip, we visited the offices of Dr. H. S. Freeman in Salem, Oregon to observe a demonstration of a "cardiovascular diagnostic unit" developed by Spatial Dynamics.

Most of 7 September was spent in travel from Atlanta to Houston and from Houston to Baker. We arrived at the offices/laboratories of Spatial Dynamics in Baker, Oregon at approximately 3:00 PM after traveling all day. Discussions regarding the EM hyperthermia system were held with Mr. Tex Yukl until 5:00 PM. The primary objectives of those discussions were to learn more about the design of the "bidirectionally focusing antenna" used as the applicator for the EM hyperthermia system and to answer some of the questions posed in Monthly Progress Report No. 1. We found Mr. Yukl to be evasive in his responses to many of the questions asked, and in particular, to questions about the theoretical design basis for the antenna. Monthly Progress Report No. 2 summarizes our assessment of what the device (antenna) appears most likely to be. Based on Mr. Yukl's answers to questions about design information in the patent document, many of the seemingly important and exact design details of the focusing antenna described therein have little, if any, theoretical basis. For example, the impedance formula given in the patent document is the formula used for computing the characteristic impedance of a twin-lead (parallel-conductor) transmission line. It was determined that the antenna does not actually focus energy in the ray optics sense. However, Mr. Yukl indicated that the dielectric lens embodiment surrounding the driven element and director rings did produce an energy

concentrating effect one-quarter wavelength distance from the driven element, in both axial directions. Discussion on the first day of the visit ended with few answers, but we did gain a better intuitive "feeling" for design basis of the antenna.

The objective of the second day's visit was to observe the EM hyperthermia system in operation and to perform the acceptance tests outlined in the attached document entitled "Intermedics/Spatial Dynamics Near Field Hyperthermia Therapeutic Device - Basic Testing." It was not possible for Spatial Dynamics personnel to demonstrate operation of the overall hyperthermia system as specified and designed because of an RF interference problem in the temperature feedback control loop. However, it was possible to operate the RF generator and amplifier in a manual mode for testing of those sections of the system and for evaluating the applicator (bidirectional focusing antenna).

Numerous problems were encountered in testing of the system's RF sections. After performing some initial measurements in the aperture of the applicator antenna using a short dipole field probe furnished by Georgia Tech, a connector/cable problem was discovered in the path from the high-power amplifier to the applicator. This problem resulted in nearly 100 percent of the RF power being reflected back into the amplifier instead of coupling to the applicator. However, the problem was intermittant and we were able to perform crude E-field measurements in dielectric phantoms (glycerol plus water in a bucket) and power density measurements in air. In both cases, these measurements were performed directly in front of the antenna's "upper" aperture and at various distances away from the aperture. The major difficulty associated with performing the RF field and power density measurements was the lack of a suitable means for reliably and accurately repositioning the measurement probes. During the measurements, the probes were hand-held and the measured values were manually recorded. Because of the crude manner in which the data were taken, significant variabilities resulted which substantially reduced the reliability of the measured results. Nevertheless, certain trends in the measured field were observed: (1) a broad peak in field intensity within the dielectric phantom was observed as the dipole probe was moved inside the phantom along the central axis of the antenna; (2) a central peak in field intensity was observed as the probe was moved within the dielectric phantom in a plane parallel to and 2 inches away from the aperture plane for the probe oriented parallel-polarized with respect to the antenna; and (3) a central null in field intensity was observed for the same conditions as in (2) but with the probe oriented cross-polarized with respect to the antenna. It is emphasized that although some useful information was gained from these measurements, it is important that careful field intensity measurements be performed for the conditions described in Monthly Progress Report No. 2 using a reliable and repeatable means for mechanical positioning of the probe(s).

During the review of the hyperthermia system's design criteria and procedures for operation, several functions and displays relevant to automatic system control and operator-system interface were noted which needed improvement. Additionally, a few physical factors in need of some attention were also noted. The recommended system modifications are summarized in the following list.

- The "site" temperature channel should provide for selection of temperature information either from a probe in the phantom tumor model or from "External Probe # 1", which could be inserted in the tumor to monitor its actual temperature.

- An "External Probe # 2" input should be added which can be switch-selected instead of the average media temperature. This would permit direct monitoring of normal tissue (skin or breast) temperature.

- Three temperature displays should be provided. These should display:

  - Systemic temperature,
  - Site or External Probe #1 temperature (switch-selected);
  - Media or External Probe #2 temperature (switch-selected).

- The system should "alarm" or "shut down" if either the media temperature (or External Probe #2) or the core (systemic) temperature exceeds a preset temperature.

- The automatic feedback power-output control loop operation should be based on a desired treatment "site" temperature which can be preset.

- A momentary-contact pushbutton switch should be provided for core temperature, media (or External Probe #2) temperature, and site (or External Probe #1) temperature such that when depressed, the "preset" temperature is displayed and that value can be adjusted via a front panel-mounted control.

- The status indicators should be made uniform so that all lamps are either extinguished or lighted for normal operating status.

- Automatic impedance matching between the RF source and applicator should be provided if it is determined that the impedance match is critical.

- The manual-automatic operation selector switch should be replaced by a key-operated switch.

- The coaxial cable between the RF source and the applicator should be relocated inside the applicator positioning arm.

- Ventilation through the RF amplifier compartment should be improved to provide adequate cooling with the system cabinet's front doors closed.

It is recommended that the above-listed system improvements be made at Spatial Dynamics prior to shipment of the hyperthermia system to Georgia Tech. However, if it is determined that the necessary modifications and improvements to the system cannot be accomplished at Spatial Dynamics, then they could be performed at Georgia Tech as an initial part of the Phase II efforts.

On the evening of September 8, we traveled to Salem, Oregon and on the following morning, we observed a demonstration of a "cardiovascular diagnostic unit" designed and developed by Spatial Dynamics. The antenna design approach in that unit was essentially identical to the approach used for designing the hyperthermia applicator. The primary difference was that the design frequency of the diagnostic unit is higher than that of the hyperthermia system. Operation of the cardiovascular diagnostic unit as a heart rate monitor was quite impressive. Waveforms similar to arterial blood pressure waveforms were also recorded; however, their possible relationship to actual arterial pressure has not been established. Thus, without further investigation, it would not be advisable to state explicitly or implicitly that the waveforms observed corresponded to the blood pressure waveform. It appears that the high quality factor of the "lens" antenna, which impaired its performance as a hyperthermia applicator, actually makes possible use of that antenna as a sensitive diagnostic tool. The antenna's high quality factor makes it sensitive to changes in impedance and therefore, motion of biological structures. Thus, the device has application as a transducer for detecting dielectric/volume changes and/or changes in the position of dielectric interfaces. The low power levels (less than $10\mu W/cm^2$) employed in the diagnostic unit preempt any question as to its safety. Further investigations with this unit need to be performed in order to establish its true usefulness. Experiments should be conducted during which simultaneous plots of the phonocardiogram, electrocardiogram, and arterial pressure are recorded in an effort to ascertain the meaning of the various components of the waveform obtained from the diagnostic unit. It is possible that such a device could ultimately prove useful for diagnosing a variety of heart diseases.

Following the demonstration, we departed Salem in an Intermedics corporate jet and arrived in Houston in the late afternoon of 9 September. A commercial air carrier was used for the final leg of the trip from Houston to Atlanta that evening.

INTERMEDICS/SPATIAL DYNAMICS
NEARFIELD
HYPERTHERMIA THERAPEUTIC DEVICE

DATE: 9/8/82

INITIAL TESTING:

AT: SPATIAL DYNAMICS, LTD. BAKER, OREGON

BY: _____

_____

_____

_____

_____

HYPERTHERMIA BASIC TESTING

A. DIRECT Rf RADIATION

1. Frequency
   a. Spec.: 240-350 MHz
   b. Actual: 338 MHz (SG504, TEK)

   COMMENTS: 3dB bandwidth was only 2 MHz (i.e. ±1 MHz either side of center frequency).

2. Tuning Range
   a. Spec.: ±10% (Actual Frequency ±10%)
   b. Actual: ±1 MHz (SG504, TEK)

   COMMENTS: Very sensitive to impedance changes because of high Q. Could be problem when load impedance changes during heating, or due to motion artifact.

3. Lens Input Power
   a. Spec.: 200 Watts RMS Max.
   b. Actual: 200 Watt Fwd (IM4190, Heath)

   COMMENTS: OK Note: Cooling of power amplifier is not adequate.

4. SWR
   a. Spec.: 1.1 to 1 or Less
   b. Actual: 1.9 @ 150 Watts (IM4190, Heath)

   COMMENTS: 150 watts forward; 15.5 watts reflected. Bad cable-connector problem existed. Often the VSWR would become extremely large, with effectively all power being reflected. This was due to the connector/cable interface at the high power RF output port and where the cable entered the lens.

5. Site Power @ λ/4 in K10 to K40
   a. Spec.: Approx. 50 mw/cm²
   b. Actual: 10mW/cm² @ 13.5W K1 (1501, Holiday)
   c. Approx: _____ K10 (K1 X 3) (Assumed)

   COMMENTS: Needs to be remeasured with system in its final configuration. We measured 10mW/cm² in air for 13.5 W net power input.

HYPERTHERMIA BASIC TESTING PAGE TWO

A. DIRECT Rf RADIATION (Continued)

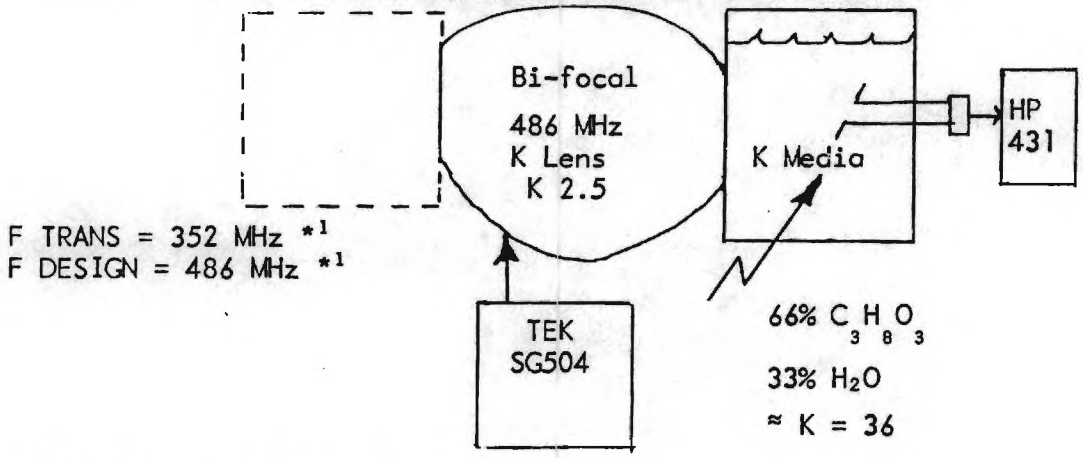
6. Spatial Dimensions (λ/2 Points)
   a. X/Y -3db in K40
   b. Actual: _____ in K1 @ 11 cms (1501, Holiday)
   c. Approx: _____ in K10 (K_3^1) (Assumed)

   COMMENTS: Refer to Final Report for project A-3528. Also, the field measurements need to be performed again at Spatial Dynamics using a mechanical positioner for positioning of field probe.

7. Maximum Power Point (Depth in K10)
   a. Spec. ≈ 5 cm's (λ/8 in K10 @ 330 MHz)
   b. Actual: Demonstrate in Fixture (HP432)
      (NOTE: Cannot be measured in K1 due to air appearing as an accellerating media to lens, K2.5, scattering the energy rapidly.)
   c. Maximum Power _____cm's in K _____@_____MHz.
   d. Approx: _____cm's in K10 (Assumed from 7b)

   COMMENTS: Needs to be determined by Spatial Dynamics and data presented to Intermedics, Inc.

FIGURE 1. DEMONSTRATION FIXTURE (K MED > K LENS)
(For determining Spatial Dimensions in Media)



*1 F TRANS is Diagnostic Operating Point, i.e. Receive

F DESIGN is Therapeutic Operating Point, i.e. Transmit

HYPERTHERMIA BASIC TESTING PAGE THREE

B. STRAY RF RADIATION

1. Electromagnetic
   a. Spec.: <5mw/cm^2 @ 5 cm's
   b. Actual: _____ mw/cm^2 (RAHAM MOD 4)
      Location of Maximum _____

COMMENTS: Difficult to determine due to RF cable problems. Needs to be measured after cable/connector problems are resolved. Revise specification to: $\leq 1 mW/cm^2$ @ 5 cm from object.

2. Line Insertion
   a. Spec: -60 db @ 200 Watts
      (117V RMS X 0.001 = 0.117V RMS)
   b. Actual: _____ V RMS Hi Line
      _____ V RMS Newtral
      _____ V RMS Ground
      At Adjacent Plug
      (5514N Sampler, AC Coupled)

COMMENTS: Not measured. No facilities at Spatral Dynamics for performing this measurement. Needs to be performed.

3. 60 HZ Ground Current
   a. Rectal Probe (Epoxy'd Yellow Springs)
   b. Device Ground Current
      1. Spec: <10 ma RMS
      2. Actual: _____ ma RMS (TEK Current Probe)

COMMENTS: Not measured. Same reason as #2. Needs to be measured before shipment of system.

   c. Chassis 60 HZ Voltage to Ground Plug
      1. Spec: <10 MV RMS (7904/7A22 TEK)
         (for Plug R of <100 milliohms)
         G.L.I.T. NOT AVAILABLE
      2. Actual: _____ MV RMS

COMMENTS: Not measured. Needs to be measured before shipment of system.

NOTE: Also need to know the total current supplied from the primary AC power source under maximum output power conditions.

HYPERTHERMIA BASIC TESTING PAGE FOUR

B. STRAY RF RADIATION (Continued)

4. Conductive Coating of Lens
   a. 60 Hz
      1. Spec: <10 ma RMS
      2. Actual: _____ ma RMS (TEK Current Probe)
   b. Rf (Coating Insulation Z)
      1. Spec: <10 V RMS @ 350 MHz

COMMENTS: Not measured. Needs to be measured by Spatial Dynamics before shipment of system.

C. ALARMS

a. Site Temperature: Alarm at set temperature +1°C
_____OK
b. Media Temperature: Alarm at Core Temperature +1°C
_____OK
_____OK Alarm at Set Temperature +1°C
c. Core Temperature: Alarm at Set Temperature +1°C
_____OK
d. Audio/Visual Indication: _____

COMMENTS: Not operational at time of testing due to feedback loop problem.
It is imperative that this be resolved and tested.

D. PORTABILITY

a. Movable over reasonably encountered floor obsticles.
_____ ✓ OK OK

COMMENTS: Packaging was well done.

E. DEMONSTRATION OF PUMP CONTROLLER FOR MAINTENANCE OF MEDIA TEMPERATURE.

Note: Needs to be demonstrated before acceptance of system by Intermedics.

A-3328

FINAL TECHNICAL REPORT
PROJECT A–3328

PHASE I DESIGN EVALUATION OF A PROTOTYPE MEDICAL ELECTROMAGNETIC HYPERTHERMIA SYSTEM

By

E. C. Burdette and D. J. Schaefer

Prepared for

INTERMEDICS, INC.
P. O. Box 617
Freeport, Texas 77541

Under

PURCHASE ORDER NO. 50203

Submitted by

BIOMEDICAL RESEARCH DIVISION
ELECTRONICS TECHNOLOGY LABORATORY

GEORGIA INSTITUTE OF TECHNOLOGY
A Unit of the University System of Georgia
Engineering Experiment Station
Atlanta, Georgia 30332

GTEES

1982

FINAL TECHNICAL REPORT

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FOREWORD

This performance assessment study was conducted by personnel of the Electronics and Computer Systems Laboratory of the Engineering Experiment Station at the Georgia Institute of Technology, Atlanta, GA 30332. Mr. E. C. Burdette served as the Project Director. The work described herein was performed under Intermedics, Inc. Purchase Order No. 50203 and was designated by Georgia Tech as Project A-3328.

This Final Technical Report concerns work performed from 12 August 1982 through 31 October 1982. It summarizes the objectives, activities, and results of a study to evaluate the design, expected performance, and potential clinical suitability of an electromagnetic heating system for hyperthermia treatment of cancer. The heating system was developed by Spatial Dynamics, Ltd. of Baker, OR for Intermedics, Inc. The authors would especially like to thank Mr. Reese Terry, Vice President for Corporate Technical Resources, Intermedics, Inc. and Mr. Tex Yukl of Spatial Dynamics, Ltd. for their significant contributions to this program effort.

Respectfully submitted,

Everette C. Burdette
Project Director

APPROVED:

James C. Toler, Chief
Biomedical Research Division

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SECTION I
INTRODUCTION

It has been demonstrated through laboratory studies and limited clinical experience over approximately a decade that hyperthermia is both a potent modifier of tumor response to ionizing radiation and, in some instances, tumorcidal in its own right. Key observations are that (1) hypoxia does not protect cells against the effects of hyperthermia as it does against ionizing radiation, (2) heat appears to damage the vasculature of tumors but not of normal tissues, resulting in preferential heating in tumors, (3) cancerous areas previously irradiated can be heated with little apparent additive inquiry to normal tissues, and (4) heat appears to inhibit repair of radiation-induced DNA injury, thereby reducing the radiation dose required to reach a specific cell-killing endpoint. In addition to its potentiation of ionizing radiation treatment, hyperthermia enhances the killing of tumor cells by certain chemotherapeutic agents.

At present, a major problem with the clinical use of hyperthermia induced by electromagnetic (EM) energy is that, with few exceptions (e.g., superficial tumors), the hyperthermia treatment of tumors in most anatomical sites is extremely difficult to plan, execute, and monitor. There has been a modest effort by academic investigators and private industry to develop equipment for EM-induced heating of tumors as well as to develop instrumentation for measuring temperature in EM fields. Although many promising hyperthermia treatment systems have been described, most systems are "homemade" and the few commercially available systems are costly. Further, many of the described systems either exist only conceptually or they lack features necessary for their effective clinical application. Therefore, a commercially available system of modest cost which provides effective hyperthermia treatment for at least one major class of tumors and which is designed for use in the clinical environment is sorely needed.

The overall purpose of the work performed during this program was to evaluate the performance and potential clinical suitability of an EM heating system for hyperthermia treatment of cancer. The heating system was developed by Spatial Dynamics, Ltd. (Baker, Oregon) for Intermedics, Inc. Reported

herein are the results of a Phase I effort consisting of a technical system design review, theoretical performance appraisal, comparison of technical design approaches used in other EM hyperthermia systems, and identification of technical/operational problems which would affect the system's use in a clinical environment.

Each of the objectives of the Phase I effort was successfully achieved. An initial system design review was performed using written (and videotaped) technical information provided by Intermedics and Spatial Dynamics. As a result of that initial review, a number of questions concerning the system design and its operation were formulated. Many of those questions were answered during a visit at Spatial Dynamics in Baker, Oregon for the purpose of testing and performance evaluation of the prototype hyperthermia system. The hyperthermia system incorporates an applicator which is unique in design. The applicator, termed a "bidirectionally focusing antenna" appears to function as a leaky cavity. Some concentration of energy seems to occur when the applicator is coupled to a lossy slab dielectric medium, but not necessarily more so than for other more conventional applicator designs. The operational bandwidth of the applicator is very narrow, resulting in high sensitivity to impedance mismatches. Unfortunately, no automatic impedance matching capability has been included in the present system. As currently configured, a few technical/operational problems exist which would impact use of the system in a clinical facility. The primary ones concern the temperature monitoring system and the automatic control functions. These are described in further detail in Section IV of this report.

Results of the initial design review of the hyperthermia system developed by Spatial Dynamics, Ltd. are presented in Section II. In Section III, the theoretical performance appraisal and a comparison to other design approaches are presented. Results of experimental evaluation of the hyperthermia system are discussed and suggested system modifications/improvements are presented in Section IV. Section V summarizes features and basic designs of several commercially-available EM hyperthermia systems. Conclusions and recommendations for the Phase II technical efforts are presented in Section VI.

SECTION II
INITIAL DESIGN REVIEW

The first stage of the Phase I study to assess the performance and clinical suitability of the referenced EM hyperthermia system consisted of a review of the system design. This initial design review was based on information provided by Intermedics, Inc. and by Spatial Dynamics, Ltd. A general description of the "Tumor Hyperthermia Therapy Device", concentrating on the physical aspects of dielectric heating, is given on the first two pages of the contract between Intermedics and Spatial Dynamics. The technical sections of that contract are reproduced as Appendix I of this report. The performance specifications of the hyperthermia system are listed in Table I.

The overall system block diagram and the schematic diagrams provided by Intermedics were helpful in examining overall system operation and in particular, system control functions, safety features, and temperature monitoring provisions. The hyperthemia system block diagram is reproduced in Figure 1 and a photograph of the prototype system is shown in Figure 2. The basic RF source configuration consists of a low-power tunable oscillator, with a variable output attenuator, which is used to drive a high-gain broadband power amplifier capable of 200 watts output. The power amplifier output signal is connected to the driven element of the applicator via a reflectometer which monitors forward/reflected power.

Automatic control of the RF output power level is provided by means of a temperature feedback control loop. A temperature monitoring probe senses the temperature in a phantom tumor bolus located in a dielectric medium having electrical properties comparable to those of normal breast tissue at the treatment frequency. The phantom tumor temperature is termed the "site" temperature and the temperature of the surrounding dielectric medium is termed the "media" temperature. The purpose of the two-phantom media is to provide a means for temperature sensing which is indicative of the actual tumor temperature without implanting probes in the actual tissue being treated. The phantoms are located adjacent to one aperture of the "bidirectionally focusing antenna" applicator and the living tissue to be heated is located adjacent to the opposite aperture of the applicator.

TABLE I

HYPERTHERMIA SYSTEM SPECIFICATIONS
(Reproduced from data provided by Spatial Dynamics, Ltd.)

A. PRIMARY RF RADIATION

- 'P' Band, 240-350 MHz. (Lens translation freq = 340 MHz, Operating freq = 246 MHz.)
- Tuning range (fine adjust) = + or - 10% of indicated frequency.
- Lens input power, maximum = 200 watts, rms.
- PA to Lens SWR = adjustable to 1.1 or better.
- Site delivered power (K=10) = 50 mW/cm^2
- Spatial dimensions: (K=10)
  - X or Y = 19.3 cm
  - Z = 0 to 5.0 cm adjustable with focus spot indicator.

B. STRAY RF RADIATION

- Less than 5 mW/cm^2 from 200 MHz to 1.0 GHz.
- AC line insertion; greater than -60 dB, 117 vac rms reference.
- 60 Hz line to ground wire leakage;
  - Rectal probe to ground = less than 10 μa rms.
  - Device ground current = less than 10 ma rms.
  - Device to ground plug pin resistance = less than milliohms.
- Conductive lens coating to ground;
  - 60 Hz = less than 10 ma rms.
  - Rf = less than 10 vrms @ 350 MHz.

C. ALARMS AND CONDITIONS

- An exceeded Site or Media temperature-set limit = Visual and audible warning.
- An exeeded Core temperature-set limit = Automatic PA shut-down.
- An exceeded Respiration or Heart set rate = Visual and audible warning

D. PORTABILITY

- Wheeled cart, with adjustable therapeutic lens, designed for patient bedside operation.

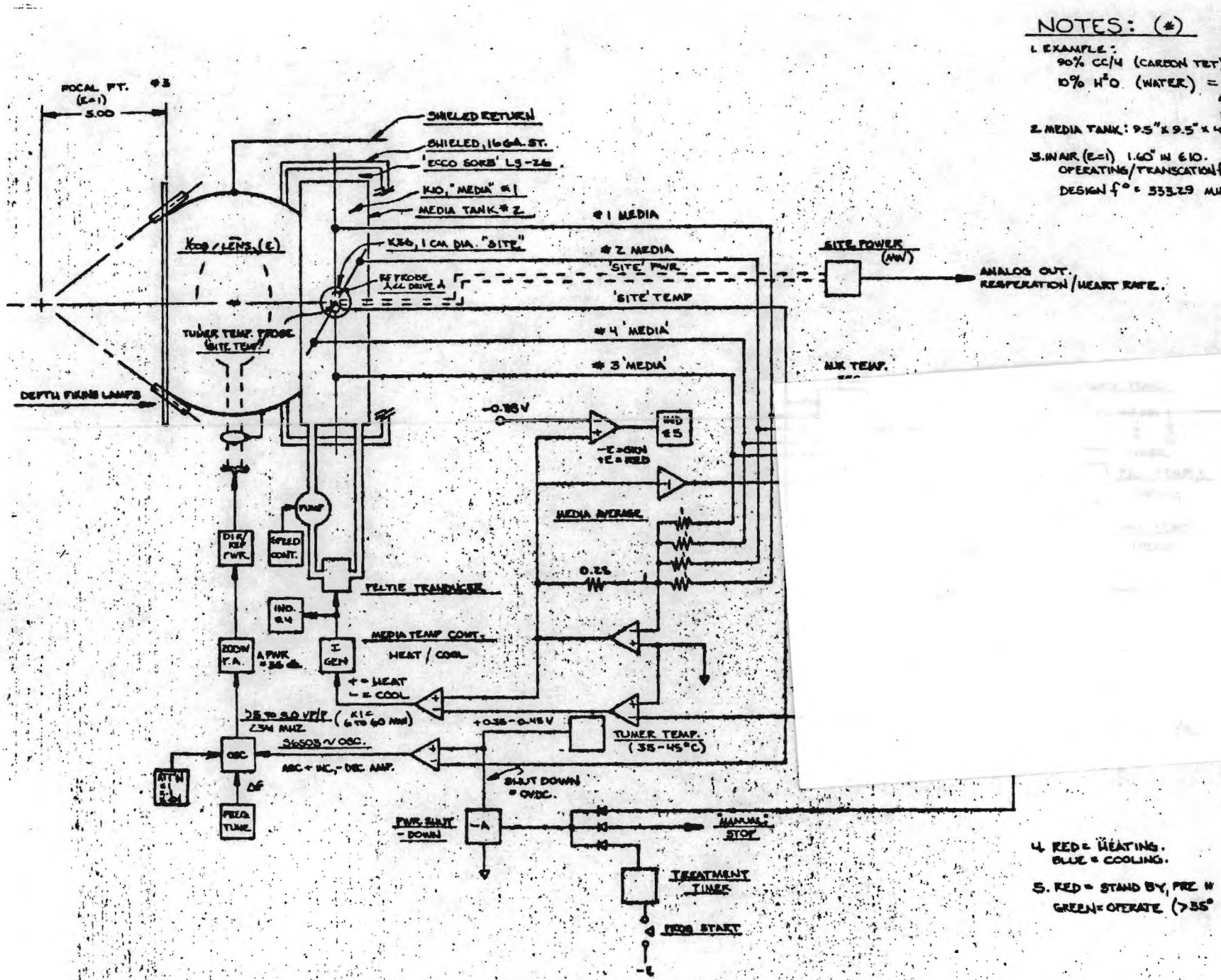

Figure 1. Block diagram of the UHF hyperthermia system reproduced from blue print provided by Spatial Dynamics, Ltd.

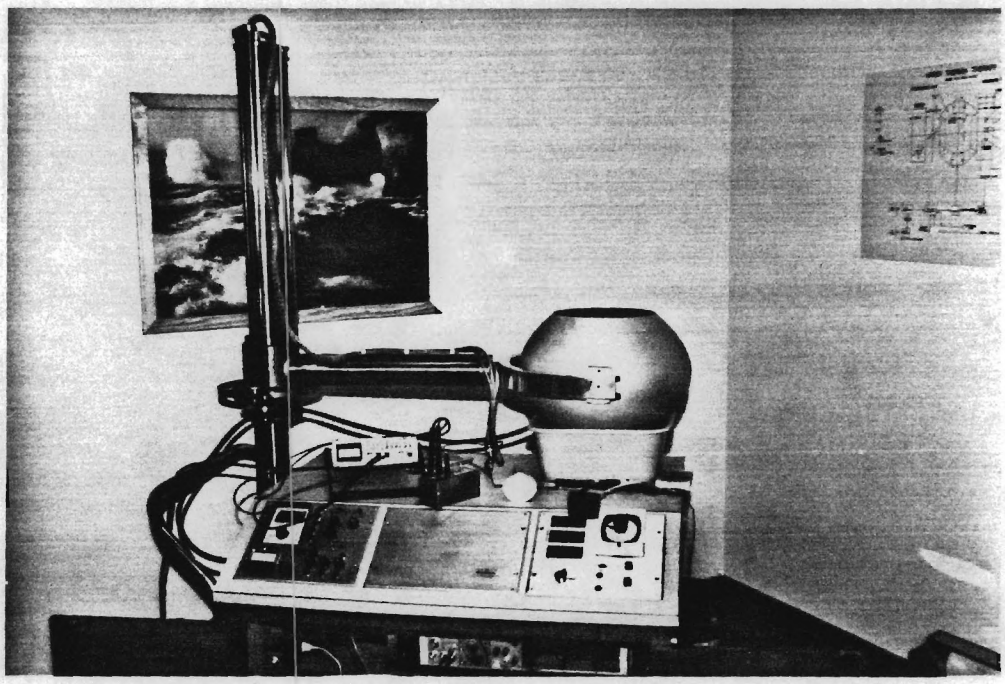

Figure 2. Photograph of the prototype of the UHF hyperthermia system developed by Spatial Dynamics, Ltd. for Intermedics, Inc.

If the dielectric characteristics and geometries of the phantom media and tissues are the same or nearly so, the temperatures measured in the phantoms are considered to be reflective of the actual tissue temperature. This is discussed further in the next section of this report. Measured site temperature in the tumor phantom is used in the temperature feedback loop to control the RF power output level. This is accomplished by differentially amplifying the voltage proportional to site temperature and a preset desired tumor temperature. The resultant output is a correction voltage indicative of the difference between the actual and set point temperatures. This control voltage sets the output level of the oscillator which drives the RF power amplifier. Starting and shutdown of the RF oscillator drive is controlled by the treatment timer, a "manual stop" override, and the overtemperature alarm signal.

An alarm condition and automatic shutdown of the system is to be accomplished if either the average phantom media temperature or the actual body "core" temperature (measured by a rectal temperature probe) exceeds a preset temperature. The average media temperature is obtained by averaging temperatures in the phantom dielectric material (within which the phantom tumor is located) measured at 4 discrete points. Any one of the 4 media temperatures can be switch-selected for display. The average media temperature is displayed and used for overtemperature control and alarm functions. The actual rectal temperature of the patient is also used as an input to the overtemperature shutdown and alarm circuitry. Both the average media and core (rectal) temperatures are used in a differential control circuit which operates a conduction-type preheater used for elevating average media temperature to a point equal to the patient's core temperature. A pump is provided for continuously circulating and mixing the liquid "normal tissue" dielectric media in order to maintain thermal equilibrium throughout the phantom media. All of the sensors used for temperature measurement in the phantom materials (site and media) are of the semiconductor chip variety which tend to have a slow response due to their relatively large mass and which tend to perturb the EM field due to the use of metallic connecting leads. Also, the system was not designed such that the RF power could be pulsed on and off so temperatures in the media/site could be sampled during the "RF off" periods. Therefore, although the general intent and schema used for RF power output control, overtemperature protection/RF shutdown,

and overtemperature alarm are quite adequate, the potential for temperature measurement artifacts extensive enough to render the system clinically unuseable is very great.

From the initial design review of the hyperthermia system based on the available design drawings, videotape, and technical descriptions, the following questions were formulated:

1. What was the design basis for the "Bidirectionally Focusing Antenna"?

2. Does the lens actually focus energy into a planar slab phantom model? If so, how is this accomplished?

3. What are the spatial locations of the half-power (3 dB) points at $\lambda/8$ and $\lambda/4$ from the lens aperture (in a K=11 medium) as compared to the half-power points in the aperture?

4. Assuming that a "focusing effect" is achieved in a planar slab phantom, what effect does the presence of an irregular geometry (such as a breast) have on the "focused" pattern?

5. (a) How is impedance matching between the source and antenna accomplished?

   (b) Is there a means by which impedance matching can be adjusted to account for patient-to-patient variations and for changes due to temperature rise, and for effect of patient movement?

6. Does the second "port" on the "lens" actually mirror image the effects at the opposing port?

7. Is this device to be used only for heating breast tumors, or other anatomical sites also? If so, which ones?

8. How are tumor heating and treatment temperature controlled?

9. Are thermistors out of the EM field? If not, how is their perturbation of the EM field taken into account? What compensation is made for any temperature measurement artifact caused by the RF field?

10. (a) Are "air gaps" going to be present between the antenna and the tissue to be heated (e.g. breast tumor), or is there to be a dielectric bolus used for improving coupling and reducing stray radiation?

    (b) If a gap is present, what method will be used to minimize stray radiation?

11. Does the tissue penetration depth of the EM field applied by this system differ significantly from the depth of penetration of an incident plane wave?

12. What shielding is provided for the system electronics? In particular, how is the power output control feedback loop protected?

13. Is it feasible to monitor heart rate and respiration (using EKG electrodes) with a high-intensity EM field present?

14. How is the optimal flow rate determined for the phantom dielectric media? By what means is the pump controlled?

15. Are there plans for surface cooling of normal tissue directly beneath the lens?

16. What does the X-Y lens controller do?

In order to perform a useful and accurate assessment of the operation of the subject EM hyperthermia system and its potential for clinical use, it was necessary to answer as many of the above questions as possible. To that end, a trip to Baker, Oregon during September 7-9, 1982 was made for the purpose of testing the prototype system developed by Spatial Dynamics. During that visit, operation of the system was observed, an attempt was made to obtain answers to the above-listed questions, and to acquire useful additional technical information concerning the design basis of the lens antenna. Useful answers to most questions were obtained and limited testing of the prototype system was performed. The results of those tests and information answering the above questions are presented in Section IV of this report.

SECTION III
THEORETICAL PERFORMANCE APPRAISAL

In this section, the expected performance of the referenced hyperthermia system based on theoretical considerations is discussed. These discussions center on the applicator and its theory of operation, since the effectiveness of the applicator design largely determines the usefulness of the system as a whole. The ability of the applicator designed for this system to "focus" or concentrate EM energy in a desired direction is discussed relative to optical focusing and other applicator designs used for EM hyperthermia.

Based on discussions with Mr. Tex Yukl of Spatial Dynamics, an examination of the applicator's design theory was performed to gain insight into what is theoretically possible with respect to energy concentration away from the antenna aperture. First, it is well known that focusing in the ray optics sense does <u>not</u> occur unless the focusing device is minimally several wavelengths across and several wavelengths thick [1]. In the system discussed here, the lens design does not meet the physical criteria necessary for focusing in the ray optics sense. Therefore, if energy concentration beyond either aperture of the bidirectional antenna does take place, it must be accomplished by some other means. Assuming that a concentration of energy at or beyond the aperture exists, the smallest spatial extent, or "width", of the concentrated energy can be determined from the plane wave expansion of the emitted complex waveform.

Any complex waveform can be expressed as the sum of different plane waves with different amplitudes and phases, and even different directions of propagation [2]. Thus, for any given direction, the resulting wave function, ψ, is a vector summation of the various plane-wave components. Letting E_i represent the individual wave amplitudes and ϕ_i the phase differences between the individual plane waves, then in a given direction the vector summation is expressed as

$$\psi = \sum_{i=1}^{n} E_i \, e^{j\,(k\cdot r + \phi_i)} \,. \qquad (1)$$

Separating the kernel (e^{jkr}) and phase terms, we obtain

$$\psi = \sum_{i=1}^{n} E_i \, e^{jk\cdot r} \, e^{j\phi_i} \,. \qquad (2)$$

The kernel can be removed from the summation to yield

$$\psi = A \; e^{jk \cdot r} \quad , \tag{3}$$

where $A = \sum_{i=1}^{n} E_i \, e^{j\phi_i}$ is a constant and k is the propagation constant. From this simple derivation, one observes that in a given direction for a single frequency, the propagating wave will be sinusoidal with a period fixed by the medium and the frequency. Thus, the half-power points will be spaced 90 degrees, or one quarter wavelength, apart. In air, at 333 MHz, the half power points would be spaced 22.5 cm apart. In a medium having a relative dielectric constant of 11, the half power points would be 6.78 cm apart. The aperture of the prototype device examined was 22.5 cm in diameter. Thus, no power density concentration would be anticipated in air; however, the power density in a medium with a relative dielectric constant of 11 would increase by a factor of 10.9, or approximately 10 dB. This appears encouraging. However, note that the same "concentration" would occur for any applicator coupled directly (beginning at the aperture) to the same dielectric medium (K = 11). Note also that the above analysis is for the ideal case. Normal diffraction from an aperture results in a pattern in which adjacent maxima are one wavelength or more apart [3], so that generally energy concentration at an extent or "width" of less than a wavelength does not occur. In view of these brief theoretical considerations, the ability of the "Bidirectionally Focusing Antenna" to effectively concentrate energy more so than conventional dielectric-loaded applicators is doubtful.

The device (antenna) examined appears to be a loop-excited, leaky cavity with some dielectric loading. The effect of the dielectric loading is unclear; however, it would appear to affect the effective electrical circumference of the excited and parasitic loops. The effect of the "director" loops (parasitic loops) is also somewhat unclear, although it is highly likely that the close spacing of the director loops may actually produce the narrow-band cavity-like characteristics of the device. A "rough" set of measurements performed on the device during our visit at Spatial Dynamics suggests that the antenna has a high quality factor (Q=170) with the center frequency at 338 MHz. As a result of this high Q, small changes in the impedance match of the antenna to the tumor (or phantom) being heated may cause serious problems in coupling the desired power to the tumor.

From the information we gathered during the visit at Spatial Dynamics in Baker, Oregon, there is little evidence to suggest that any "focusing" of the emitted field from the bidirectional antenna is taking place. Clearly, no focusing in the geometrical optics sense can take place in a device of such small dimensions relative to the operational wavelength. Considering the device as a leaky cavity, fringing fields from the device may peak at some distance in a dielectric medium, but such an effect would be highly dependent upon the dielectric medium's geometry. Further, analysis of this effect would require the use of numerical techniques on a mainframe computer and the results would be different for each specific dielectric material and geometrical configuration.

Testing of the device in a relatively small volume of phantom media (in terms of skin depth) causes standing waves to be produced from reflections at air/media and media/air interfaces. These standing waves would have half-power "points" one-quarter wavelength apart. The locations of standing wave maxima would change as a function of the depth (thickness) of the phantom media and could be mistaken as focusing of EM energy.

It is important to note that no fundamental theoretical reason was found to completely justify the assumption that changes in the impedance match at one "focal" distance would be mirrored at the other one, or that temperatures at the two sites would identically track. Perfect symmetry in electrical properties, geometrical properties, and in thermal properties are necessary for the two sites to truly "mirror" each other. Each site is affected by changes in the dielectric properties of the other site in a complicated way. Intuitively, it appears that an "inverse" relation may exist between the two sites. However, the information (or opportunity to experimentally evaluate) provided to us was <u>not</u> sufficient to determine the relation between the two sites. Because of dielectric, geometrical, and thermal differences, it is likely that the relation is highly complex. Further, because of the lack of EM isolation, it is probable that the "bifocal lens" would not perform as well as a more conventional system utilizing a 3 dB power splitter and two separate applicators (one for the phantom and one for the patient). The difficulty of developing and maintaining a phantom whose thermal and electrical properties, as well as geometry, track those same properties for a tumor being treated, is very great, even if changes in tumor blood flow and necrosis are neglected. It may not be

possible, and if possible, it would be extremely difficult, to design a practical system which dymanically tracks thermally and electrically the tumor being heated.

SECTION IV
EXPERIMENTAL PERFORMANCE APPRAISAL
AND
RECOMMENDED SYSTEM IMPROVEMENTS

This section presents the results of measurements performed during a visit at Spatial Dynamics in Baker, Oregon specifically for the purpose of testing the prototype hyperthermia system. Several types of information about the system were gathered, including a "crude" set of E-field distribution measurements. Results of the experimental measurements performed and, where appropriate, reference to other design approaches are presented. Finally, system modifications/improvements are suggested.

A. Experimental Performance Appraisal

It was not possible for Spatial Dynamics personnel to demonstrate operation of the overall hyperthermia system as it was designed, nor was it possible to check many of the design specifications, because of an RF interference problem in the temperature feedback control loop. This control loop interference rendered the automatic control and alarm/shutdown sub-systems unusable. However, it was possible to operate the RF generator and amplifier in a manual mode for testing of those sections of the system and for evaluating the applicator (bidirectional focusing antenna).

Numerous problems were encountered in testing of the system's RF sections. After performing some initial measurements in the aperture of the applicator antenna using a short-dipole field probe furnished by Georgia Tech, a connector/cable problem was discovered in the signal path from the high-power amplifier to the applicator. This problem resulted in nearly 100 percent of the RF power being reflected back into the amplifier instead of coupling to the applicator. However, the problem was intermittant and during periods when the system was working, the reflected power was approximately 10 percent of the total forward power. Thus, we were able to perform crude E-field measurements in dielectric phantoms (glycerol plus water in a bucket) and power density measurements in air. In both cases, these measurements were performed directly in front of the antenna's "upper" aperture and at various distances away from the aperture. The major difficulty associated with performing the RF field and power density measurements was the lack of a

suitable means for reliably and accurately repositioning the measurement probe. During the measurements, the probe was hand-held and the measured values were manually recorded. Because of the crude manner in which the data were taken, significant variabilities resulted which substantially reduced the reliability of the measured results. Nevertheless, certain trends in the measured field were observed: (1) a broad peak in field intensity within the dielectric phantom was observed as the dipole probe was moved inside the phantom along the central axis of the antenna; (2) a central peak in field intensity was observed as the probe was moved within the dielectric phantom in a plane parallel to and two inches away from the aperture plane for the probe oriented parallel-polarized with respect to the antenna; and (3) a central null in field intensity was observed for the same conditions as in (2) but with the probe oriented cross-polarized with respect to the antenna. Plots of these preliminary results are shown in Figures 3 and 4. It is emphasized that although some useful information was gained from these measurements, it is important that careful field intensity measurements be performed using a reliable and repeatable means for mechanical positioning of the probe(s). Recommendations as to the field intensity measurements which should be performed were made in Monthly Progress Report No. 2 and they are repeated in the following paragraph.

The most appropriate method to determine the field pattern from the bidirectionally focusing antenna would be to systematically measure its radiated field pattern at various distances from the aperture. A recommended method for characterizing the radiated field pattern would be to measure the field intensity over a plane directly in front of the aperture and orthogonal to the antenna's axis. Measurement points in the plane should be spaced one quarter wavelength apart. Measurements should be performed at several distances from the aperture. These should minimally include measurements in or near the plane of the aperture itself and at distances of 1/4, 1/2, and 1 wavelength away from the aperture. Such measurements should be performed both in air and in a test dielectric medium having dielectric properties equivalent to normal breast [4], both with and without the "opposite aperture" terminated in a dielectric phantom. Carefully performed measurements for the four cases stated above at the suggested distances from the aperture (which are referenced to a single maximum field intensity) should provide satisfactory information for assessing the true character of the emitted

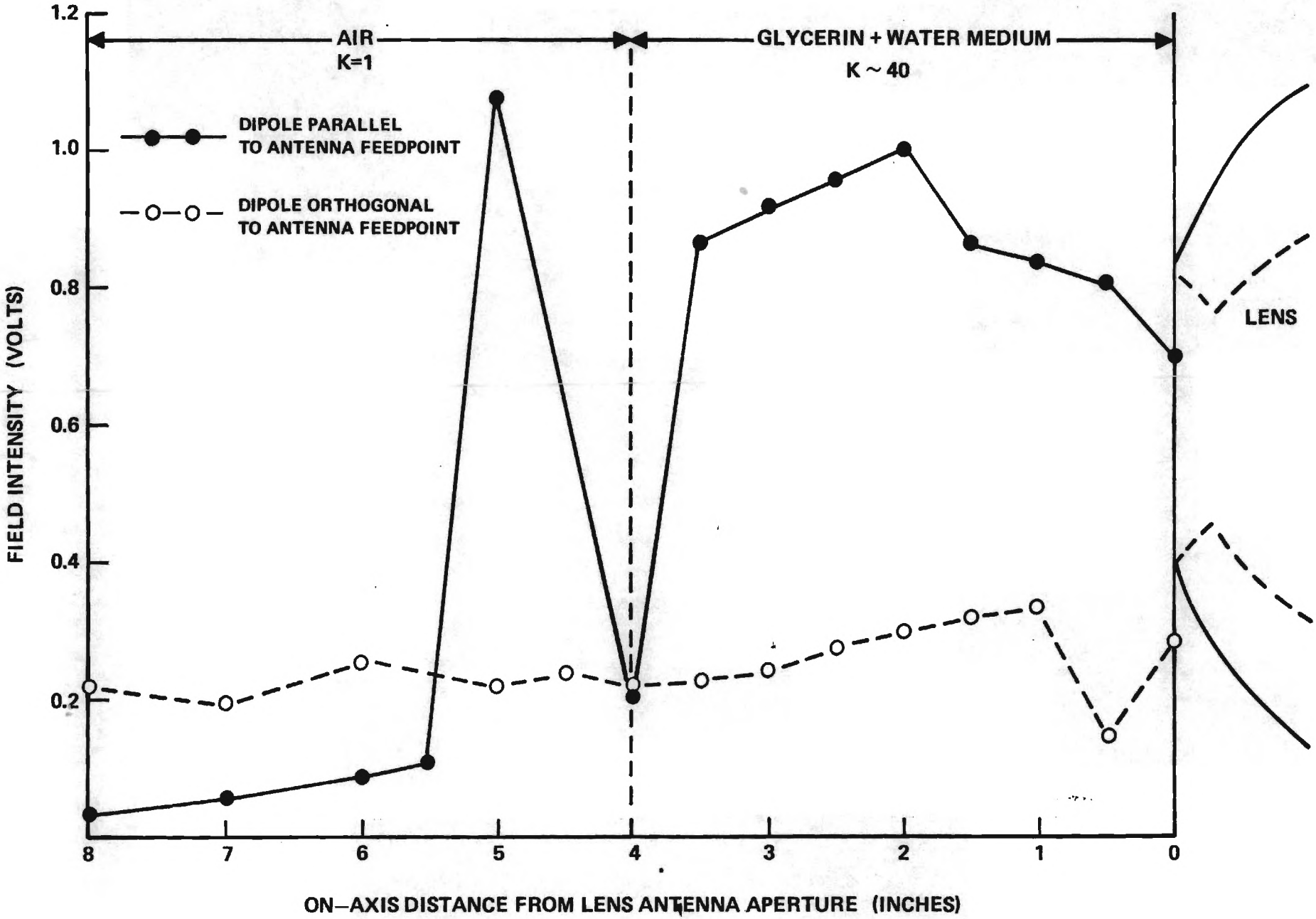

Figure 3. Results of preliminary field intensity probe measurements along the central axis of the bifocal lens antenna coupled to phantom dielectric medium for the dipole probe oriented parallel and orthogonal to antenna feedpoint. Position of lens aperture indicated in drawing.

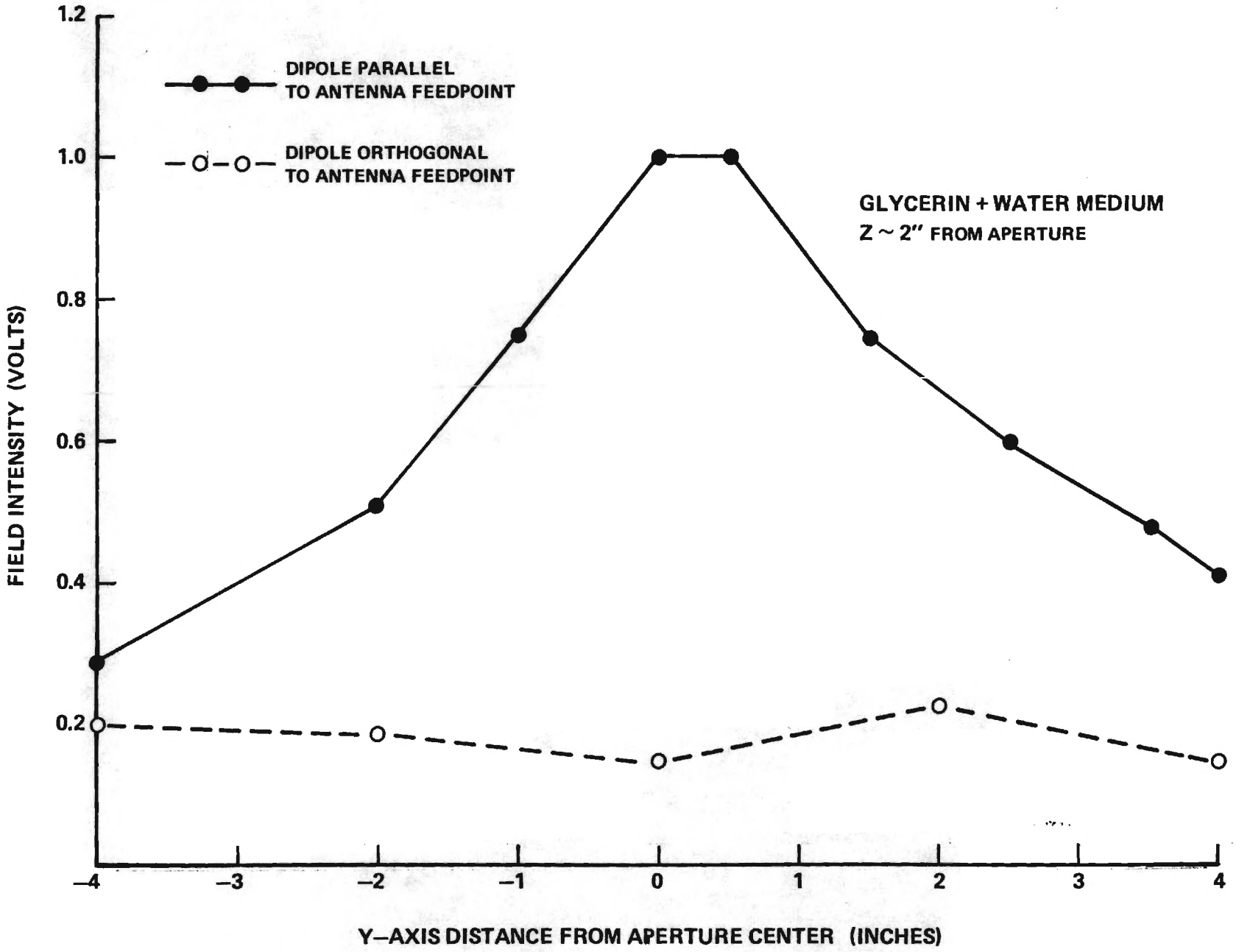

Figure 4. Results of preliminary field intensity probe measurements performed in a phantom dielectric medium over a plane parallel to and 2 inches in front of the "lens" aperture. Two principal axis Y-cuts (through X=0) shown for dipole probe oriented parallel and orthogonal to antenna feedpoint.

field pattern and whether or not any significant energy concentration takes place.

The rough field patterns from the "bidirectionally focusing antenna" were compared to theoretical and experimental results published by Guy [5] for the case of a finite linearly polarized rectangular aperture source in direct contact with a bilayered tissue. The aperture source configuration and tissue geometry used in Guy's analysis are shown in Figure 5. The origin of the coordinate system is located in the center of the aperture and the direction of propagation is along the positive Z axis directed down into the tissues perpendicular to the interfaces. The electric source field in the plane of the aperture is oriented parallel to the X-axis (i.e., in the same direction as the "b" dimension of the aperture). Guy's results for "relative heating" at different depths due to an a=12 cm by b=16 cm aperture source reproduced from Reference 5 are shown in Figure 6. The relative heating is related to the electric field intensity by

$$P_{1,2}(x,y,z) = \sigma_{1,2} \left| E_{1,2}(x,y,z) \right|^2 \qquad (4)$$

where $P_{1,2}$ is the relative heating (i.e., absorbed power) in the two different media (1 = fat, 2 = muscle), $\sigma_{1,2}$ is the electrical conductivity of each respective medium, and $E_{1,2}$ is the electric field intensity in each medium. Figure 6 shows the relative heating curves for a 2-cm thick fat layer above a semi-infinite muscle layer (see Figure 5) at various frequencies. Only half of the symmetrical heating curves in the X-Z plane (along the b aperture dimension) are shown with fat plotted on the right of the symmetry axis and muscle plotted on the left. Relative heating curves in the X-Y plane (along the a aperture dimension) for 918.8 MHz are shown in Figure 7 (reproduced from Reference 5). The relative heating curves for the X-Z plane at 433.2 MHz, 750 MHz, and 918.8 MHz (Figure 6) have a cosine squared variation for muscle, but not for fat. Similar curves for the Y-Z plane at 918.8 MHz (Figure 7) have a cosine squared variation for both fat and muscle. From these results, one can readily make the observation that the maximum power deposition, and relative heating, occurs in the tissues located in the region central to the aperture. For the 12-cm by 16-cm aperture, the maximum (and useful) heating occurs within the central 6-cm by 8-cm area. Thus, the major power absorption (i.e., to the -3 dB points) occurs in the central

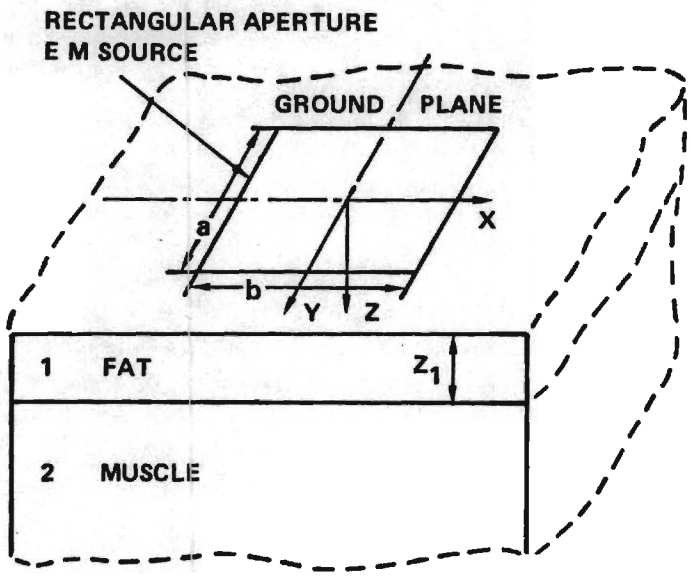

Figure 5. Rectangular aperture source and tissue geometry (redrawn, from Reference 5).

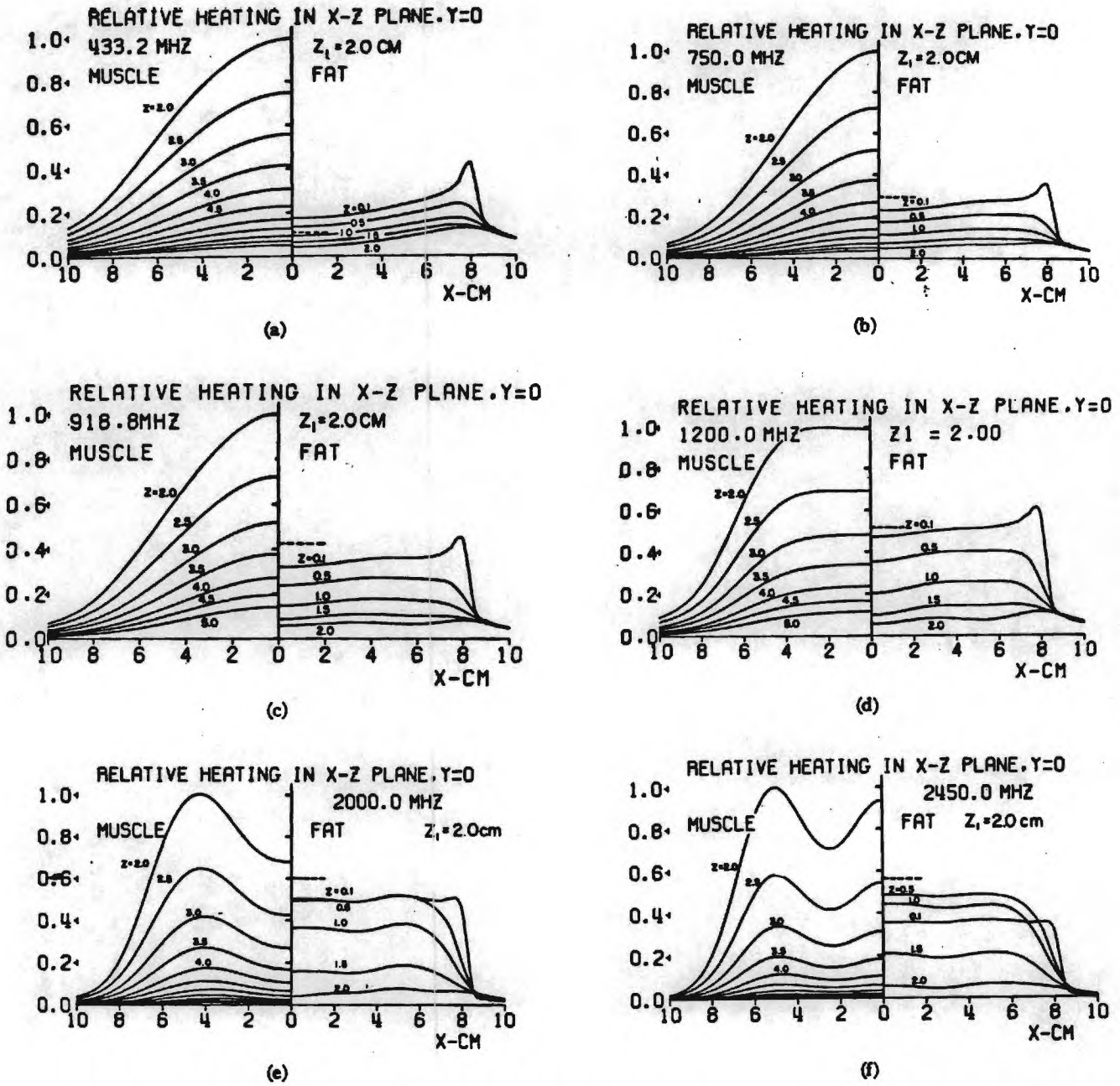

Figure 6. Relative heating patterns for TE-mode aperture source with a=12 cm, b=16 cm, and Z_1=2.0 cm in X-Z plane for frequencies from 433 MHz to 2450 MHz (reproduced from Reference 5).

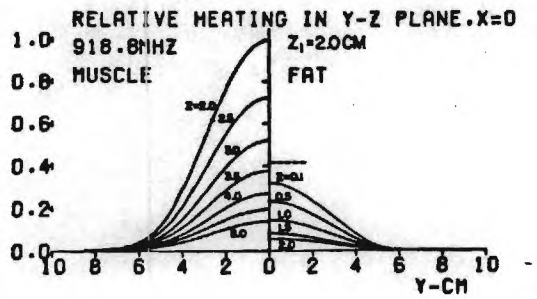

Figure 7. Relative heating patterns for TE_{10}-mode source with a=12 cm, b=16 cm, and Z_1=2.0 cm in Y-Z plane (reproduced from Reference 5).

25 percent of the aperture area. This result compares very favorably with the rough measured results for the bifocal lens antenna (Figure 4). Those results indicate that the same power level distribution for the bifocal lens is in the central 26-30% of the aperture area. Therefore, it would appear that there is little, if any, advantage to be gained in terms of "focusing" by using the bifocal lens antenna. However, we must be careful in coming to a conclusion too quickly because (1) the test dielectric media (bilayered versus a single medium and different dielectric properties for the fat-muscle model and glycerol-water phantom) were different for the two cases, (2) different frequencies of antenna operation were used, and (3) the experimental data on the bifocal lens antenna were the result of very crude measurements. Therefore, the bifocal lens (i.e., the bidirectionally focusing antenna) should be thoroughly tested and reliable, reproducible field measurements made before making final conclusions and recommendations.

Field intensity measurements of the bifocal lens antenna were recently performed (November 1982) by personnel at Spatial Dynamics. These measurements were performed using a Raham Model 484 power density monitor and a mechanically-stable means was used for accurately positioning the measurement probe during the measurement tests. The bifocal lens antenna, operating at 317 MHz, was terminated on both sides in a K=5 dielectric medium which was 7 inches deep. The test conditions and resulting data provided by Spatial Dynamics are attached as Appendix II of this report. Their results are qualitatively similar to the results (Figures 3 and 4) from the crude measurements performed during our site visit at Spatial Dynamics, Ltd. in September 1982. The intensity measurements along the antenna's axis compare very favorably (compare Figure 3 with the "Z-axis Power Distribution" results in Appendix II). The intensity measurements over a plane parallel to and approximately two inches away from the lens aperture also agree qualitatively. However, close examination of the results measured at depth "C" (2.2 inches from the antenna aperture) in Appendix II indicates that the field intensity (1) is quite uniform over distances 2 inches from the aperture center and (2) reaches the -3 dB level at a distance of 5.6 inches from the aperture center. The second result means that the majority of power (to the -3 dB level) is concentrated in the center 38% of the aperture area (when operating into a K=5 load). Therefore, the energy concentration of the bifocal lens measured by Spatial Dynamics personnel is actually less than that obtained from the earlier

crude measurements. Further, conventional rectangular apertures, properly coupled to the dielectric medium, concentrate the same energy within an even smaller area (approximately the central 25%). Finally, the Z-axis "focusing" is most probably due to a standing wave in the dielectric medium. The depth, or thickness, of the medium should be a minimum of 1-2 wavelengths (in the medium) to reduce the influence of standing wave phenomena on the actual field intensity.

The measurements made demonstrated that the hyperthermia system will heat a phantom, though the power amplifier failed during the test. To gain some insight into the efficiency of the system, heating of phantoms was performed. If there were no heat losses to the surroundings and if the temperature of the liquid were uniform, then from static calorimetry we may say that the absorbed power, P, is related to the elapsed time, Δt, the mass of the fluid, m, the specific heat of the fluid, C, and the temperature rise, Δt, in the following manner:

$$P = \frac{(4.18)\ m\ C\ \Delta T}{\Delta t}. \qquad (5)$$

Glycerin has a specific heat of 0.6 cal/g^{o}C while that of water is 1.0. The density of water is 1.0 g/cm^{3} while that of glycerin is 1.3 g/cm^{3}. In an experiment performed at Spatial Dynamics, a solution of 60% glycerin and 40% water was used as the loads. Since the experiment was crudely done, the values of density and specific heat for water were used in the calculations. The upper load (5 liters of liquid) experienced a 3.8^{o}C temperature rise, while the lower load (6 liters of liquid) experienced a 6.5^{o}C temperature rise. The forward power used in this experiment was 150 watts, the measured reflected power was 15.5 watts, and the RF power was left on for 45 minutes. Our rough calculations indicated that the upper tank was receiving 29.4 watts of power while the lower tank was receiving 64.8 watts for a total of 94.2 watts. Since the net power was 134.5 watts, the efficiency appears to be roughly 70%. Some of the unaccounted-for energy was dissipated in the lens and the cable and some may be an artifact of the experiment. If some 40 watts was being dissipated, then a better, more efficient design approach should be implemented.

The voltage standing wave ratio, S, may be expressed in terms of the forward power, P_f, and the reflected power, P_r, as:

$$S = \frac{1+\sqrt{P_r/P_f}}{1-\sqrt{P_r/P_f}} = \frac{\sqrt{P_f}+\sqrt{P_r}}{\sqrt{P_f}-\sqrt{P_r}} . \qquad (6)$$

Since objects supporting standing waves tend to radiate and to increase their other losses, the standing wave ratio should be minimized. Stray radiation was very high when a high standing wave ratio was measured, though the stray radiation was acceptable at other times. In a clinical setting, further reductions in the stray radiation may be achieved by using a microwave bolus filled with lossless material of the same dielectric constant as the tissue, arranged to present a flat surface to the incident field to minimize scattering.

The results of our field probing indicate that off-axis maxima and on-axis minima do exist (Figures 3 & 4), although they may be related to standing waves. The pattern from the device is approximately the same as would be anticipated from a loop with a circumference of a wavelength or more [1]. The measurements were made without positioners or even shielded cable, and so are suspect. No large focusing effects were observed outside the bifocal lens antenna.

B. Recommended System Modifications/Improvements

During the review of the hyperthermia system's design criteria and procedures for operation, several functions and displays relevant to automatic system control and operator-system interface were noted which needed improvement. Additionally, a few physical factors in need of some attention were also noted. The recommended system modifications are summarized in the following list.

- The "site" temperature channel should provide for selection of temperature information either from a probe in the phantom tumor model or from "External Probe # 1", which could be inserted in the tumor to monitor its actual temperature.

- An "External Probe # 2" input should be added which can be switch-selected instead of the average media temperature. This would permit direct monitoring of normal tissue (skin or breast) temperature.

- Three temperature displays should be provided. These should display:

  - Systemic temperature;
  - Site or External Probe #1 temperature (switch-selected);
  - Media or External Probe #2 temperature (switch-selected).

- The system should "alarm" or "shut down" if either the media temperature (or External Probe #2) or the core (systemic) temperature exceeds a preset temperature.

- The automatic feedback power-output control loop operation should be based on a desired treatment "site" temperature which can be preset.

- A momentary-contact pushbutton switch should be provided for core temperature, media (or External Probe #2) temperature, and site (or External Probe #1) temperature such that when depressed, the "preset" temperature is displayed and that value can be adjusted via a front panel-mounted control.

- The status indicators should be made uniform so that all lamps are either extinguished or lighted for normal operating status.

- Automatic impedance matching between the RF source and applicator should be provided if it is determined that the impedance match is critical.

- The manual-automatic operation selector switch should be replaced by a key-operated switch.

- The coaxial cable between the RF source and the applicator should be relocated inside the applicator positioning arm.

- Ventilation through the RF amplifier compartment should be improved to provide adequate cooling with the system cabinet's front doors closed.

It is recommended that the above-listed system improvements be made at Spatial Dynamics prior to shipment of the hyperthermia system to Georgia Tech. However, if it is determined that the necessary modifications and improvements to the system cannot be accomplished at Spatial Dynamics, then they could be performed at Georgia Tech as an initial part of the Phase II efforts.

At present, there is no way to adjust the impedance match of the system. Since patient movement, temperature, tissue necrosis, and blood flow all affect the tumor dielectric properties, it is essential that an impedance matching device (perhaps automated) be added to the hyperthermia system before clinical use. A potentially severe problem is that this "leaky cavity" has a high quality factor (in this case $Q = \frac{f_2 - f_1}{f_o} = 170$, where f_2 and f_1 are the half power points and f_o is the center frequency). As a result, small changes in the impedance match may cause tremendous problems in coupling power to the tumor.

The temperature measurement system to be used with this device should be improved. Integrated circuit sensors are too bulky to give fast responses to temperature changes and consequently, overshoot with the temperature controller is very likely. In addition, the existing probes will perturb the electric field (although this may not be terribly important in an implanted probe). A serious problem is that the electric field will interfere with the electronics of the temperature measurement and controller circuits. This may be avoided by measuring temperature only when the field is turned off (and holding the reading when the field is on) or by using one of the fiber optic systems. Finally, the temperature controller should be developed to bring the temperature up to the control temperature as rapidly as possible without overshoot. This may require a good deal of work to achieve.

The hyperthermia system examined has several serious drawbacks: the loss of half the power due to the bifocal lens antenna system, the lack of any large concentration of energy by the "lens", the lack of an adequate temperature monitoring system, the lack of a dynamic (perhaps automated) impedance matching system, and the high quality factor of the lens (resulting in a device very sensitive to changes in impedance). On the positive side, the system will heat tumors and can do this with an aperture smaller than would normally be required. However, it is not likely to be significantly better than other contact hyperthermia systems employing dielectric loaded horn or circular waveguide antennas.

SECTION V

COMMERCIALLY-AVAILABLE EM HYPERTHERMIA SYSTEMS

In this section, the features and basic designs of several commercially-available EM hyperthermia systems are summarized and appropriate comparisons made to the system designed by Spatial Dynamics, Ltd. for Intermedics, Inc. This brief review of commercially-available systems focuses primarily on the energy modality used, frequency range, the applicators available with each system, type of temperature monitoring employed (if any), and the type and degree of sophistication of system control provided. The systems reviewed herein are manufactured by the BSD Corporation, Clini-Therm Corporation, Hyperthermia Division of Henry Electronics, Inc., Societe d'Equipments Medicaux (SEM), ERBE, and Bioelectromagnetics Corporation. Relatively few commercially-manufactured systems are actually in use at the present time, and all EM hyperthermia equipment are currently being utilized clinically for investigative work in hyperthermia. The majority of systems in use are either "homemade" or consist of off-the-shelf general-purpose EM sources, thermometry systems, etc. assembled for operation as a "system". Of the commercially-manufactured systems, those apparently in the greatest number of clinics, hospitals, and university centers are manufactured by ERBE, BSD Corporation, and Henry Electronics, Inc.

Perhaps the most sophisticated of the presently-available commercial systems are those manufactured by BSD Corporation (Salt Lake City, UT). The basic system offered is the BSD-1000. A variety of EM applicators and other options are available for use with the basic system.

An applicator configuration for heating deep-seated tissues was recently developed (1981) by BSD Corporation which is known as an "Annular Phased Array" applicator. The features (specifications) of the BSD-1000 system are listed in Table II. The standard system operates over the 50-1000 MHz frequency range with options for extending the range down to 10 MHz and up to 2,500 MHz. The system can accommodate operation of from one to four applicators simultaneously, all of which are of the radiating-field type. The applicators are coaxially-fed dielectric-loaded rectangular (or square) aperture devices based on the design described by Guy [5,6]. Several applicators of different aperture sizes and operating frequency ranges are provided

TABLE II

BSD-1000 SYSTEM SPECIFICATIONS
(From published brochure, BSD Corporation)

A. MAJOR SUBSYSTEMS

1. Microwave Power Generation
2. Electronic Data Processing
3. Control Feedback

B. MICROWAVE POWER GENERATION SUBSYSTEM

1. Frequency Range: 50-1000 MHz (options available to extend range down to 10 MHz and up to 2500 MHz)

2. Power Output: 85-100 watts maximum (continuously adjustable from 0.25 watt to maximum level)

3. Power Efficiency Control: computer control of microwave power transfer to subject material (i.e., auto impedance matching)

4. Applicators: dielectric-loaded rectangular aperture applicators (up to 4 may be operated simultaneously)

5. Electromagnetic Chamber: absorber-lined 6'W x 8'D x 8'H shielded room

C. ELECTRONIC DATA PROCESSING SUBSYSTEM

1. Microcomputer: Zilog Z-80 CPU, 32k Bytes memory, three mini-floppy disk drives (75k Bytes each), color and B&W video displays, printer/plotter.

2. Automatic Control: preprogrammed system initialization, safety monitoring, automatic shutdown, automatic frequency tuning and impedance matching.

3. Data Gathering: real-time display on video monitors, data storage on mini-floppy disks, hardcopy output on printer/plotter.

D. CONTROL FEEDBACK SUBSYSTEM

1. Biological Feedback: CPU-controlled closed-loop automatic temperature and RF power level control.

2. Temperature Probes: High-resistivity thermistor sensors with non-metallic leads, 1.1 mm diameter.

with the system. Each applicator can operate over a reasonably broad frequency range because automatic tuning, or impedance matching, of the applicator and the EM power source is incorporated in the system. This automatic impedance matching is controlled by the central processing unit. The "annular array" applicator consists of several rectangular water-loaded radiating-field applicators arranged in an annular ring configuration with each applicator oriented such that the emitted energy is directed centrally. The annular array is not a true phased array, but instead relies on superposition of fields from the individual applicators in the central region of the annular ring to achieve greater energy deposition than is achieved with a single applicator. The BSD applicators also feature a surface cooling system which keeps skin temperature near normal while deeper tissues are being heated.

One attractive feature of the BSD-1000 is its temperature monitoring system. Up to 16 temperature probes may be monitored by the central processor. The temperature probes provided are those originally designed by Bowman [7,8]. They are flexible, small in diameter (1.1 mm), and they are non-perturbing to EM fields. Thus, normal tissue and tumor temperatures may be monitored during hyperthermia treatments without the usual problems associated with temperature measurements in a high-intensity EM field. The central controller uses the measured temperature information at the monitored sites to control the output power of the EM source for the purpose of maintaining a desired setpoint temperature.

In several respects, the BSD-1000 is similar to the system designed by Spatial Dynamics, Ltd. Radiated-field type applicators are used, temperature monitoring is provided, and automatic safety and temperature setpoint controls are provided. However, there are also several important differences. The applicator designs for the two systems are significantly different and there exists very little information upon which to base a decision as to which design is actually better suited for clinical use. The adjustable frequency range of the BSD system allows greater flexibility in obtaining the desired depth of penetration than is possible with a single-frequency system. The temperature probes used for monitoring temperature in the BSD system are far superior to those used by Spatial Dynamics, and a skin cooling system for preventing cutaneous burns is incorporated in the BSD system. Also, the BSD system has many operator-oriented features such as color graphics video display of temperature information, patient data record keeping capability,

floppy disk data storage, and a printer/plotter for hard-copy output. Finally, it is important to examine cost. The BSD system is very expensive (approximately $150,000). It is quite reasonable to expect that a somewhat more modest system that is significantly lower priced would be quite competitive even if some of the convenience features such as color graphics, etc. were omitted. However, such a system could not compromise on controlled-heating capability, nor could accuracy/reliability of temperature monitoring be slighted in favor of lower price.

Clini-Therm Corporation (Dallas, TX) recently announced the introduction of three new systems for hyperthermia treatment/research. Their Mark I is a manually-operated 915 MHz microwave system; the Mark II is a manually-operated ultrasound system; the Mark III is a manually-operated combined microwave/ultrasound system. All three systems are to be available in January 1983. The thermometry system provided with the Clini-Therm systems is the GaAs fiberoptically-coupled temperature probe developed by Christensen [9]. The thermometry probes with monitoring electronics can be purchased in groups of four up to 12 probes, each probe is only 0.6-mm diameter, and claimed temperature measurement accuracy is $\pm$ 0.1 ^{o}C. These temperature sensors are non-perturbing and are not affected by EM fields. Although temperature-monitoring probes are provided, these three Clini-Therm systems are manually operated, i.e., no automatic setpoint temperature control is provided. Therefore, to insure proper operation and patient safety, it is imperative that these systems be operated by only highly-skilled personnel. One applicator is provided for each modality (microwave or ultrasound). The microwave applicator is a coaxially-fed dielectric-loaded waveguide. Clini-Therm product literature states that modular expansion capabilities will soon be available for the Mark I, Mark II, and Mark III systems. Expansion capabilities include additional ultrasound generators and applicators, wide frequency range microwave sources, patient (skin) cooling system, systems computerization, and automatic control of tumor temperature and maximum normal tissue temperature. No specific date of availability of these expansion features was announced by Clini-Therm.

In many respects, the features incorporated in the EM hyperthermia system developed by Spatial Dynamics overshadow the features of the Clini-Therm Mark I microwave hyperthermia system. However, the Mark III system with both microwave and ultrasound modalities could potentially provide better overall tissue heating capability than the Spatial Dynamics system.

Further, if the modular expansion capability options materialize as claimed by Clini-Therm, their system would provide significant capabilities (e.g. computer treatment control, graphics display, printer/plotter, etc.) not presently incorporated in the Spatial Dynamics system. However, it should be noted that in the past, Clini-Therm has had problems delivering their advertised systems. Comparing the Spatial Dynamics system with the Clini-Therm Mark I, we observe that both are single-frequency microwave systems and both use radiated-field type applicators. The differences, however, are many. The Mark I system operates at 915 MHz, which means that the penetration depth of the radiated energy is likely to be less than that obtainable using the Spatial Dynamics system. The applicator designs are also different, with the Mark I using a more conventional dielectric-loaded end-launched rectangular waveguide applicator. The Mark I is a totally manual system and does not provide the site temperature setpoint capability or the over-temperature alarm/shutdown capability incorporated in the Spatial Dynamics system. However, as is the case with the BSD system, the Clini-Therm system thermometry is far superior to that presently incorporated in the Spatial Dynamics system. Clini-Therm indicates that the Mark I will sell for just under $50,000, and the Mark II for under $75,000. However, it is suspected that after the more useful modular expansions are added to these systems, the overall system price will probably approach $150,000.

The Hyperthermia Division of Henry Electronics, Inc. (Los Angeles, CA) sells an EM hyperthermia system known as the Magnetrode. This system operates at a fixed frequency of 13.56 MHz and the source output power is manually adjustable over the 10-1000 watt range. Two applicator types are provided: surface direct-contact electrodes and cylindrical solenoid electrodes. Three sets of surface contact electrodes of approximately 50, 100, and 225 cm^2 surface areas are provided. These electrodes incorporate their own skin surface cooling system, but an external circulating coolant machine or water source is required. The type of heating produced by these surface contact electrodes (applicators) is resistive, i.e., tissue heating is due to ohmic losses. Three solenoid electrodes are also provided. These consist of a 20-in diameter cylindrical electrode, a 10-in diameter cylindrical electrode, and a 10-in inside diameter "doughnut". All three of these electrodes are single-turn solenoids which produce tissue heating by induction [10]. Manually-adjustable impedance matching between the RF power source

and various applicators is provided in the system. The thermometry provided with the Magnetrode system consists of a 6-channel Yellow Springs Instruments (YSI) Telethermometer and standard thermistor probes with metallic wire leads. No automatic setpoint temperature control is provided and there is no automatic overtemperature alarm/RF shutdown feature. The only "automatic" control is a treatment timer which can be preset for a desired "RF on" period.

The methods used for coupling EM energy to tissues by the Magnetrode are quite different from the method used in the Spatial Dynamics system. The operating frequencies of the two systems (13.56 MHz versus 338 MHz) are very different as are the applicator designs employed. The Magnetrode heats either through ohmic losses (resistive heating) in the tissues or by induction. The Spatial Dynamics system heats via a radiated EM field which is absorbed by the tissue. Each of these EM heating modalities has advantages and disadvantages, and the one most appropriate for a specific case is dependent upon multiple factors, including tumor location, depth, volume, etc. However, it should be noted that problems with cutaneous burns have been associated with direct contact electrodes. Further, induction heating of biological tissues is known to be inefficient because of their general non-magnetic nature. Thermometry capabilities in the two systems are similar. Both the Magnetrode and the system developed by Spatial Dynamics use thermistors for temperature measurement. The Magnetrode has somewhat better flexibility in that the six probes may be placed wherever desired (e.g. multiple sites in tumors) and the Spatial Dynamics system provides for only one site temperature measurement point. However, the Spatial Dynamics system does provide an automatic control loop based on desired site temperature and an overtemperature alarm/shutdown feature. The Magnetrode has neither of these features and the safety of their system is wholly dependent on the operator. Because conventional thermistors with metallic leads are used in both systems, the thermometry provisions in both can be viewed as being equally poor and inadequate. The Magnetrode is priced at approximately $60,000.

The HLI-500 hyperthermia system offered by SEM (LaCelle St. Cloud, France) is in many respects similar to the Henry Electronics Magnetrode, except that only contact-electrode type applicators are provided and thermocouples are used for thermometry. The system operates at a frequency of 13.56 MHz and has adjustable output power over the 0-400 watt range. The

applicators provided are soft, direct contact electrodes which are made of an electrically conductive "tissue" which can be cut to the dimensions of the zone to be treated. No specific information regarding impedance matching was included in the company's product literature, but is was stated that "reflected power is adjustable or maximum 10 percent". Thermometry provided with the HLI-500 system consists of 12 thermocouples inside of 5-cm long, 1-mm diameter sterilzable needles. A maximum of 6 thermocouples can be simulataneously connected to the system strip-chart recorder through a thermocouple selector which incorporates an RF interference filter. The system is completely manual and therefore, safety and heating efficacy are highly operator-dependent. Cost information for the HLI-500 system was not included in the available product literature.

Microwave diathermy sources and applicators which are manufactured by ERBE in West Germany are being used on a relatively widespread basis for EM hyperthermia. These systems operate on the 433 MHz European diathermy frequency. Output power from these sysems is variable over the 0-200 watt range and three types of applicators are available for use with the 433 MHz EM sources. The three applicator types are termed the "roundfield" applicator, the "long-field" applicator, and the "cradle" applicator. Detailed design information was not available. The roundfield applicator appears to be a cylindrical cavity open on one end and coaxially-fed at the opposite end. The long-field applicator appears to be a reflected-backed 433 MHz dipole antenna. The ERBE cradle applicator is a folded-dipole-fed dual corner reflector. No thermometry system is provided with the ERBE diathermy system. No adjustable (manual or automatic) impedance matching is provided and system operation is totally manual. The only actually favorable aspect of the ERBE systems are their operating frequency, 433 MHz, which can be used for reasonably efficient heating at "medium" penetration depths. A domestic company, Technology Applications Group, Inc. (Boulder, CO) manufactures and sells a patient therapy couch which is non-metallic and specifically designed for use with the ERBE systems. That firm also distributes the ERBE diathermy systems in the United States. No price information for the ERBE systems was included in the available product literature.

The final EM hyperthermia system included in this review of commercial systems is the Model C101 microwave thermotherapy system developed by the Bioelectromagnetics Corporation (Rockville, MD). To our knowledge, only

a few of these systems have been built. The overall system consists of a 0-100 watt adjustable output single frequency (2450 MHz) microwave source, circular and rectangular waveguide applicators, a multi-channel temperature monitoring system, and computer-controlled operation. The principal limitation of this system is the very small useful penetration depth of the EM energy at 2450 MHz. Because of the limited penetration depth (less than 2 cm in muscle) and power level (100 watts or less), the system is really only useful for treating superficial lesions. Optional intracavity and interstitial needle applicators are claimed to be available. These applicators could make it possible to heat deeper lesions with this system, provided that a needle could be inserted into a tumor at a known site without other complications. The Model C101 hyperthermia system does incorporate a non-perturbing temperature monitoring system using high-resistivity thermistor probes similar to those developed by Bowman [7,8]. Also, computer control of the system provides automatic heating of tissues to a preset temperature. A printer/plotter is also included with the system. The overall basic system cost is $65,000.

In summary, the EM hyperthermia system developed by Spatial Dynamics, Ltd. has the potential to compete favorably against other EM hyperthermia systems presently available if (1) the "bifocal lens" applicator can be demonstrated to effectively heat controllable tissue volumes, (2) the present temperature sensors are replaced by non-perturbing temperature probes, (3) the "mirror image" normal tissue/tumor phantom for non-invasive temperature monitoring is either determined to be efficacous or eliminated from the system, (4) electronic and RF problems with the automatic setpoint tumor temperature control and automatic overtemperature alarm/shutdown are corrected, and (5) the overall system is competitively priced relative to other available systems. Comparing the systems reviewed in the preceding paragraphs, the BSD systems are the most sophisticated, and the most expensive. The Clini-Therm modular systems are a clear contender if the expansion capabilities are indeed made available at reasonable cost. The Henry Electronics Magnetrode is unique in that it is presently the only commercially-available system offering inductive heating. However, the Magnetrode lacks significantly in other important areas such as temperature monitoring, automatic system control, and predictability of the thermal distribution within the tissue(s) being heated. The SEM HLI-500 system offers nothing innovative and is limited

in many respects. The ERBE diathermy systems are attractive from two viewpoints: lower price and frequency of operation. The applicators available with the system leave much to be desired and their RF leakage is great. Further, all aspects of system control and temperature monitoring must be provided by the user and somehow interfaced with the ERBE equipment. Therefore, the ERBE equipment is severely limited in the overall sense. The Model C101 microwave thermotherapy system developed by the Bioelectromagnetics Corporation offers significant features with respect to automatic control and thermometry. However, the single microwave frequency limitation (2450 MHz) makes the system virtually useless for all but superficial lesions. Based on the information gleaned from reviewing several EM hyperthermia systems, the following comments seem appropriate. The key features of a successfully marketable EM hyperthermia system appear to include:

1. An applicator(s) capable of heating a controllable tissue volume which operates at frequencies which permit medium-to-deep tissue penetration;
2. Thermometry which is either non-invasive or utilizes multiple non-perturbing (and non-perturbed) temperature sensors;
3. Automatic control of output power to attain and maintain tissue heating at a preset temperature;
4. Automatic system shutdown in the event a preset maximum normal tissue temperature is reached or if excessive applicator leakage occurs;
5. Automatic impedance matching between the EM power source and the applicator(s);
6. Modularized future system expansion capability; and
7. A moderate, competitive price.

It is possible that with further development the Spatial Dynamics EM hyperthermia system could provide these key features and be competitive in the hyperthermia system market. Our conclusions and recommendations are given in the next section of this report.

SECTION VI

CONCLUSIONS AND RECOMMENDATIONS

The principal attractions of the EM hyperthermia system developed by Spatial Dynamics are its potential ability to safely heat deep-seated tumors by focusing energy in the desired region and to possibly non-invasively monitor tumor and normal tissue temperatures by measuring the temperature in a mirror image phantom if the system performs as intended. However, the prototype system we examined at the offices and laboratories of Spatial Dynamics in Baker, Oregon in September 1982 falls short of these goals and did not meet the key desirable system features listed at the end of Section V of this report. The entire thermometry system needs to be replaced with one which utilizes either non-perturbing temperature probes or minimally-perturbing probes and RF pulsing to permit temperature measurements during "RF off" periods. The automatic control electronics need to be optimized for agility of the preset temperature closed-loop control and the panel controls/indicators need to be optimized with respect to operator-machine interface. Because of the frequency and load impedance sensitivity of the applicator, an automatic tuning (i.e., impedance matching) network needs to be included as part of the system. With regard to the bifocal lens applicator, it was stated previously in this report that it is not clear why the device should focus EM energy. Based on a brief comparison of crude field measurements made on the lens to the Guy applicator [6], the bifocal lens applicator does not concentrate EM energy more so than conventional dielectric-loaded applicators. In addition, even if the bifocal lens applicator did concentrate EM energy, the problems associated with making a dynamic phantom to simulate the tumor and normal tissue properties would likely prove to be insurmountable. If that indeed is the case, then the phantom side of the cavity should be closed off so that all of the EM source power can be used to heat the actual tumor. In that event, the potential advantages of the applicator design used in the Spatial Dynamics system would be focusing (if it can be shown) and the relatively small aperture of the device with respect to the wavelength employed. It is important that the EM field patterns and heating effectiveness of the bifocal lens applicator be thoroughly characterized before making a final decision whether to proceed or not to proceed with further development, clinical testing, and eventual manufacturing and sales of the system.

Based on the results of the Phase I evaluation efforts described in Sections II through V of this report, a number of tasks which need to be performed have been identified. These tasks are directed toward successful completion of a Phase II effort consisting of actual laboratory testing and evaluation of the referenced EM hyperthermia system. The following tasks comprise the recommended Phase II efforts.

1. Experimentally determine the EM field distribution in a plane orthogonal to the antenna's axial direction at the aperture and at distances of 1/4, 1/2, and 1 wavelength away from the aperture both in air and in material simulating breast tissue using E-field and H-field probes;
2. Experimentally determine the distribution of EM power absorption and steady-state thermal distribution in simulated human tissues (breast tissue phantoms) exposed to the bidirectionally focusing antenna applicator;
3. Examine the field in the proximity of the bifocal lens applicator coupled to simulated tissue to determine the levels and extent of any stray radiation which may exist;
4. Examine the impedance match of the applicator under varying load conditions to determine whether or not automatic impedance matching is necessary;
5. Investigate possible methods for widening the bandwidth of the bifocal lens applicator;
6. Compare thermal distributions obtained in phantoms obtained using the bifocal lens applicator to thermal distribution obtained using more conventional hyperthermia applicators (i.e., the Guy applicator [6]);
7. Identify and recommend a method or methods for fast, non-perturbing and non-perturbed tissue temperature monitoring during EM hyperthermia;
8. Investigate the agility and overall suitability of the existing automatic tumor temperature setpoint controller using simulated tissue phantom models and if needed, investigate improved techniques for temperature setpoint control;
9. Compare the tracking of temperature in the "mirror image" phantom to actual measured tumor temperature in an animal model and recommend action to be taken with regard to that approach;

10. Experimentally investigate the use of a dielectric "bolus" to improve impedance matching and reduce stray radiation; and
11. Perform the system modifications/improvements recommended in Section IV if they are not completed by Spatial Dynamics, Ltd.

It is anticipated that the tasks recommended above would be performed over a 4-6 month period, with the exception of Task 11 which will require an additional 2 months to complete.

SECTION VII
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6. J. F. Lehmann, A. W. Guy, J. B. Stonebridge, and B. J. deLateur, "Evaluation of a Therapeutic Direct-Contact 915-MHz Microwave Applicator for Effective Deep-Tissue Heating in Humans", IEEE Trans. Microwave Theory Tech., Vol. MTT-26(8), 1978, pp. 556-562.

7. R. R. Bowman, "A Temperature Probe for RF Heated Material", Proc. 1975 Microwave Power Symposium, Waterloo, Ontario, Canada, May 1975, pp. 172-173.

8. R. R. Bowman, "A Probe for Measuring Tempeature in Radio-Frequency -Heated Materials", IEEE Trans. Microwave Theory Tech. Vol. MTT-34, 1976, pp. 43-45.

9. D. A. Christensen, "An Optical Etalon Temperature Probe for Biomedical Applications", Proceedings of the 28th Annual Conference on Engineering in Medicine and Biology, Vol. 17, 1975, p. 249.

10. F. K. Storm, R. S. Elliott, W. H. Harrison, and D. L. Morton, "Clinical RF Hyperthermia by Magnetic-Loop Induction: A New Approach to Human Cancer Therapy", IEEE Trans. Microwave Theory Tech., Vol. MTT-30(8), 1982, pp. 1149-1157.

APPENDIX I

TECHNICAL SECTIONS OF CONTRACT
BETWEEN SPATIAL DYNAMICS, LTD.
AND INTERMEDICS, INC.

Intermedics Inc.

August 9, 1982

Mr. Everette C. Burdette
Biomedical Research Division
Engineering Experiment Station
GEORGIA INSTITUTE OF TECHNOLOGY
Atlanta, Georgia 30332

Dear Cliff:

I have enclosed for your general information, the technical sections of the contract between Spatial Dynamics and Intermedics for the development of a hyperthermia device. The specifications enclosed define the required performance of the device. Cost figures have been deleted.

Please feel free to call if you require additional information.

Sincerely,

Reese Terry, Vice President
Corporate Technical Resources

RT/dkl

Enclosure

O. Box 617, Freeport, Texas 77541 • Phone: (713) 233-3611 • Telex: 792503

Obtain Medical file

SPATIAL DYNAMICS, Ltd.

TUMOR HYPER-THERMIA THERAPY DEVICE

Proto-type completion budget

Date: December 14, 1981, budget valid to March 1, 1982
By: T. Yukl, Director

I. Project description:

A surgically non-invasive technique for selectively heating high di-electric constant tissue to cell death temperature without raising the temperature of surrounding healthy tissue having significantly lower di-electric constants is proposed.

These conditions exist when tumorous tissues (having di-electric constants of 30-40) surround or are surrounded by fatty tissue, bone or other physiological materials with di-electric constants of 8 to 10. Breast tumors are an ideal example of these conditions.

A new, patented, near-field technique exists which can substantially confine electro-magnetic radiation in the microwave frequency spectrum (wavelengths of 1 to 100 cm's) to the near-field (dimensions less than one wavelength). This technique, along with its unique patented absorbant lens, maximizes the radiation at a location approximately 1/8 wavelength from the exit face of radiating lens. The radiation diminishes exponentially from this point and is 3 db down (½ the maximum power level) ¼ wavelength away in any direction. The physical dimensions of this confined space are, of course, determined by the propagation velocity of the energy in the material being irradiated. Since propagation velocity is inversely proportional to di-electric constant, the volume of material involved increases as di-electric constant decreases. The energy absorbtion rate, and hence temperature rise of the material is directly related to di-electric constant since the wavelength of the radiation gets smaller

as di-electric constant increases. This phenomenon means a high di-electric constant media surrounded by a low di-electric environment will increase in temperature faster (in direct relation to the ratio of difference in di-electric constant) than the environment when radiated by a plain wave (for field) of electro-magnetic radiation in the micro-wave region. This difference in temperature rise is further enhanced by the "focusing" action of this unique near-field technique.

Provisions are supplied for holding and measuring the temperature at the maximized location for a programed period of time. Sufficient power is available to the irradiated site to reach and sustain cell-death temperatures (approximately 44 deg. centigrade) indefinitely. Automatic shutdown and audio alarm conditions indicate, or occur, when the temperature at the half-power points, or the patient's core temperature, exceeds safe limits. A standard rectal temperature probe is the only mechanical connection to the patient.

This proposed six month budget carries the project to the completion of the proto-type device only, and testing the unit electrically to insure it meets design specification.

A research project in a competant medical institution, clinically testing the device and insuring compliance with applicable regulations is the responsibility of Intermedics, Inc. Spatial Dynamics will cooperate with Intermedics, Inc. through its consulting agreement to implement such a program and carry it to a successful conclusion.

II. Device specificotions;

A. RF Rodiotion, direct theriputic.

1. 'P' Bond, 240-350 Mhz. (Lens iranslotion freq= 340 Mhz, Operoting freq= 246 Mhz.)
2. Tuning ronge (fine odjust) = + or - 10% of indicoied.
3. Lens input power, moximumu = 200 wotts, rms.
4. PA to Lens SWR = Adlustoble to 1.1 or better.
5. Site delivered power (K 10)= 50 mw/cm^2
6. Spotiol deminsions: (K 10)
   a. X or Y = 19.3 cms.
   b. Z = 0 to 5.0 cms odjustoble with focus spot indecotor.

B. Stroy RF rodiotion

1. less thon 5 mw/cm^2 from 200 Mhz to 1.0 Ghz.
2. Ac line insertion; greoter thon -60 db, 117 voc rms referonce.
3. 60 Hz line to ground wire leokoge;
   a. Rectol probe to ground= less thon 10 uo rms.
   b. Device ground current= less thon 10 mo rms
   c. Device to ground plug pin resistonce= less thon mill-ohms.
4. Conductive lens cooting to ground;
   a. 60 Hz = less thon 10 mo rms.
   b. Rf = less thon 10 vrms @ 350 Mhz.

C. Alorms ond conditions;

1. An exceeded Site or Medio set limit = Visuol ond oudible worning.
2. An exceeded Core locking set limit = Automotic PA shut-down.
3. An exceeded Resperotion or Heort set rote= Visuol ond oudible worning

D. Portobility;

Wheeled cort with odjustoble theriputic lens designed for potient bedside operotion. Refer to control ponel drowings for odditionol informotion.

III. Proto-type cost;

A. Stort up ond mointoinonce cost to be returned to Powers Medicol Systems for Dec.1-31 operotion----------[redacted]

B. Capitol proto-type items purchased by Powers Medical Systems and on-hand:
   1. Cosine 350 Mhz. lens (Altek, Ind)----------
   2. Equipment cabinet----------
   3. AR 200HA 200 watt P bond amplifier----------
   4. SG 503 P bond generator, Tektronix----------
   5. Heathkit bi-directional wattmeter----------
   6. Lens yoke and control mechanics----------

C. Application Patent, estimate to completion. Work performed by Kolish, Hartwell, Dickenson of Portland, Oregon----------

D. Electronic components or sub-assemblies;
   1. Displays----------
   2. Readouts----------
   3. RF 'Plumbing' (GR airline, etc)----------
   4. Tempreture probes (Yellow Springs)----------
   5. RF Probes----------
   6. Special components (Peltie devices, etc)----
   7. Normal components----------
   8. Isolation transformer----------
   9. RF line filtering----------

E. Artwork;
   1. Etched circuit cards (10 items, 5 each)-----
      (photo, drill, etch and mask)
   2. ECB layout labor----------
   3. Front panels (6 items at 400.00 ea)----------
   4. Schematics, diagrams, and renderings----------

F. Mechanics and outside contracts;
   1. Media phantom tank, pump and lines----------
   2. Shields and uwave absorbant----------
   3. Chassis' and enclosures----------
   4. Dummy load/Lens travel nest----------

G. Shop-time labor (see attached Spatial Dynamics annual operating budget)

In-house facilities: Electrical design, Mechanical design, Drafting, Wiring, Building, Check-out and De-bug.

923 hours (6 month scheduled completion)----------

H. Proto-type implementation support; (1982)
   1. Travel expenditures----------$
   2. Consulting rates (additional), see Intermedics/Spatial Dynamics consulting agreement.

IV. Total Project costs; (SEE NOTES BELOW)

A. III:A through III:H----------

B. On-hand provided by Powers Medical Systems---

C. Remainder required by Spatial Dynamics-------

V. Method of payment;

A. Initial at start of project---------- Spatial Dynamics

B. 12 payments every 2 weeks of---------- Powers Medical
   First payment to commence 2 weeks after 'A. Spatial Dynamics

VI. Delivery date; 24 weeks after reception of V:A

VII. Reporting proceedure; Spatial Dynamics will furnish written reports each two (2) weeks of the on-going project showing PO's of capital expenditures and breakdown of operating expenses.

VIII. Acceptance validation:

for Intermedics, Inc. _____ Title: Assistant Dir. Date: 1/12/82

for ~~Spatial~~ Dynamics, ~~Ltd.~~ _____ Title: [illegible] Date: 17 Dec '81

-NOTES-

1. Budget includes a 10% margin for unforseen expenditures. This will appear in bi-weekly reports as "ADMINISTRATION SUPPORT".

2. Support to Spatial Dynamics from Powers Medical Systems for 1 Dec. to 31 Dec. 1981 is refundable to PMS out of IV:C. PMS will render to Spatial Dynamics a report of its expenditures to be refunded by this budget. Support from PMS will terminate 31 Dec. 1981. Normal termination expenses of employees (vacation pay, etc.) will not be refunded by this budget.

December 1, 1981

Tumor Hyperthermia Device , Sub-assembly/component breakdown.

I. Electronic Components by Sub-Assembly

A. Receiving media and site monitor

1. Media/core temperature analogy

a. Peltie transducer

[illegible]

(2) Peltie current driver

(3) Feedback amplifier

(4) Patient core temperature buffer

(5) Media temperature averaging amplifier

(6) Pre-heat/operate indicators

(7) Pump drive/speed control

(8) Media temperature probes and buffers (4)

(9) Pump and tank mechanics

(10) 'K'10 media fluid.

2. 'Site' power monitor

(1) Phant K36, 1 cm tumor

(2) Constant current RF insertion probe

(3) Conversion amplifier

(4) Power readout, mw.

(5) Analog waveform buffer

3. 'Site' temperature monitor

(1) Site temperature probe

(2) Site temperature conversion amplifier and buffer

4. Read-out select

(a) Solid state switch module (5 pos.)

(b) Secondary temperature readout

(c) Media-temperature readout

(d) Core-temperature readout

5. Peripheral physiological outputs

(a) Heart rate

(1) 'R' wave detector

(2) Rate readout output buffer

(b) Respiration

(1) Filter and detector

(2) Rate readout output

6. RF drive comparitor
   (a) Digitial oscilator control
   (b) Alarm feedback amplifier
   (c) Tumor temperature conversion amplifier
   (d) "Site" temperature feedback amplifier
   (e) Output comparitor and buffer
7. 'P' band RF generator (vco) (off-shelf item)
   (a) Ext. amplifier control input
   (b) Ext. frequency control input
   (c) Selectable 'range' attinuator
8. 200 watt. 'P' band amplifier. (off-shelf item)
9. Power monitor, foward and reverse. (off-shelf item)
10. Airline, couplers and RF 'plumbing'
11. Alarm modual
   (a) Alarm level comparitor
   (b) Audio "gong"
   (c) Condition indicators
12. Power supplies
   (a) Analog supply
   (b) Digital supply
   (c) RF supply
   (d) Isolation transformer
   (e) RF line filtering
   (f) Patient safety ground current monitor
13. Displays and patient chart data
   a. Strip chart recorder (tumer tem.)
   b. Visual display C.R.T. with X/Y/Z/ amplifiers

II., Mechanics

A. 'P' band 1/cos lens, with;
   1. Parasite elements
   2. Dummy load and tunning fixture
   3. Drive element Z transformer and coupler
   4. Lens mounting yoke assembly
B. X/Y lens controller
   1. See attached parts list
C. Cart and equipment housing
   1. Wheels, castings, and brakes
D. Front panels, chassies, and enclosures

III. Artwork

A. Etched circuit boards

1. RF control module
2. Treatment/alarm module
3. Readout/display module
4. Status/depth module

B. Front panels

1. RF control module
2. Treatment/alarm module
3. Readout/display module
4. Status/depth module
5. Power supply and ground current monitor

C. Electronic schematic diagrams

D. Electronic parts list

E. ECB lay-out dollys.

F. Mechanical diagrams

G. Mechanical parts list

9-23

Rf CONTROL

DRIVE CONTROL

FEEDBACK

MAN

GAIN

Attn.

X1

X.1

X.01

P.A. OUTPUT

BI-DIRECTIONAL WATTMETER

FWD

off

BATT

Refl.

TUNING

DEC

INC

SITE POWER

CAL FIXTURE

0.5

1.0

$\mu W/cm^2$

PHANTOM

0.5

1.0

1

10

100

MW/cm²

100

10

1

$\mu W/cm^2$

HI LEVEL W/cm²

ATT'N. (FULL SCALE)

OUTPUTS

OSC. FREQ. MON.

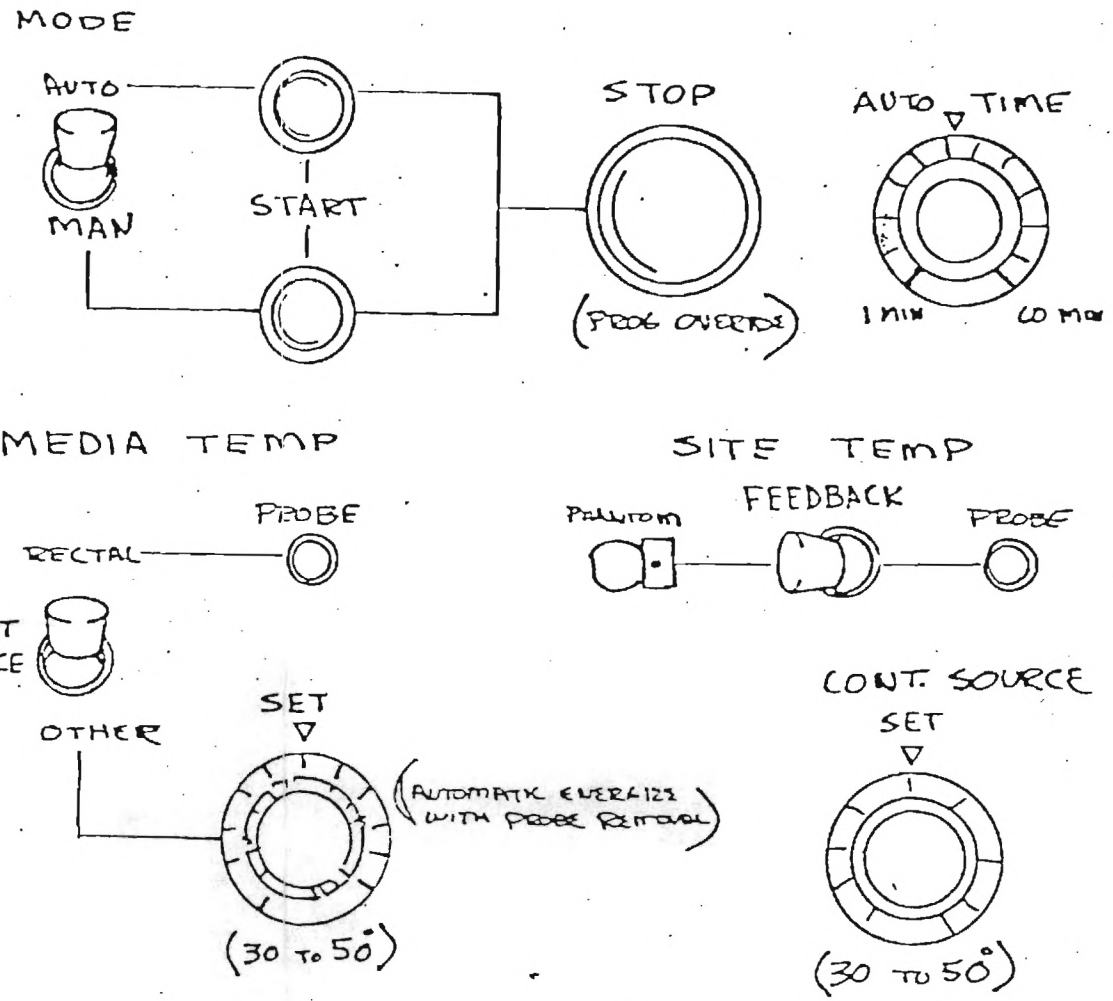
P.A.

SITE PWR

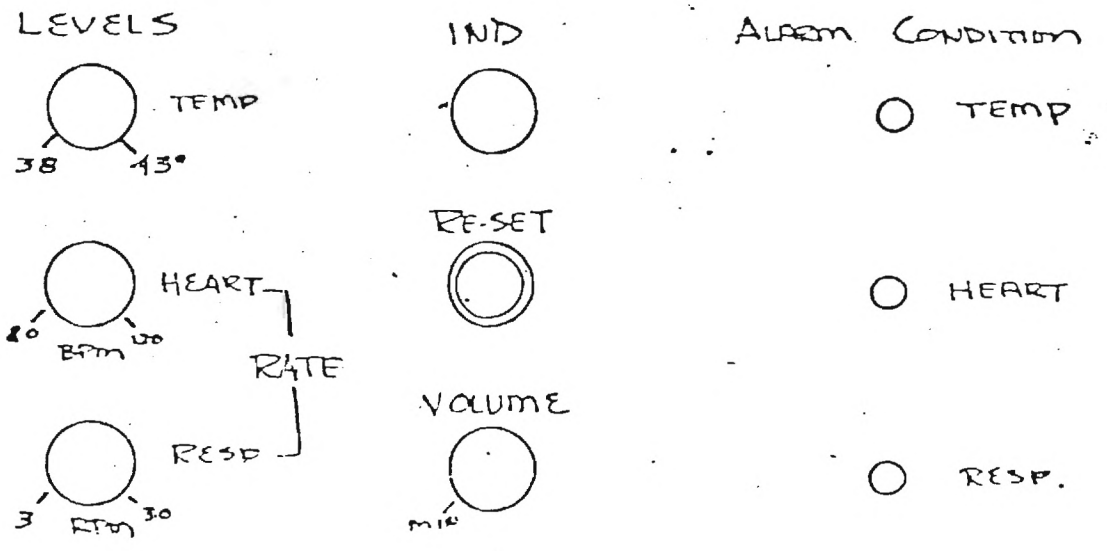
MAN. INVE WHEN BLINKING.

E

TREATMENT PROGRAM



ALARMS



STATUS

MODE (MEDIA AVE TEMP)

STB'Y.

MEDIA < 35°

OPERATE

MEDIA > 35°

MEDIA DRIVE

HEATING

COOLING

DEPTH

off ON

LAMPS

REF

SET

DEPTH, CMS

MEDIA K

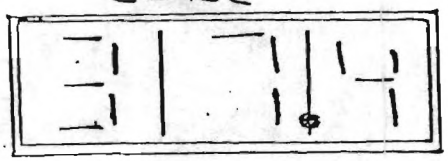
5 50

DI-ELECTRIC CONSTANT (SCALING)

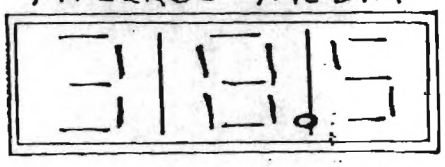
READ OUT

PRIMARY TEMPRETURES

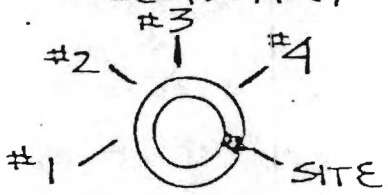
CORE

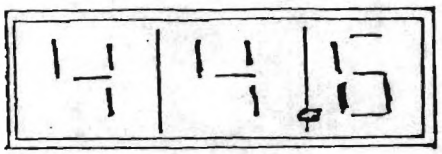


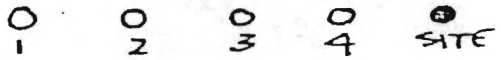
AVERAGE MEDIA



SECONDARY TEMPRETURES

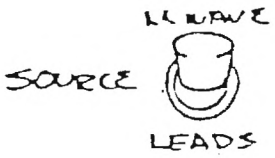


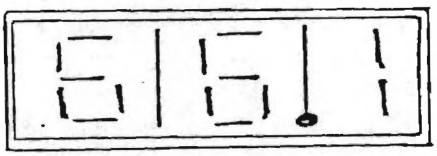




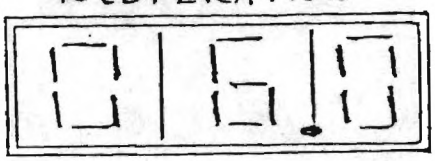
(TRANSLATED) PHYSIOLOGICAL

HEART RATE



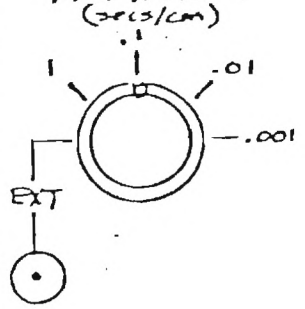


RESPERATION

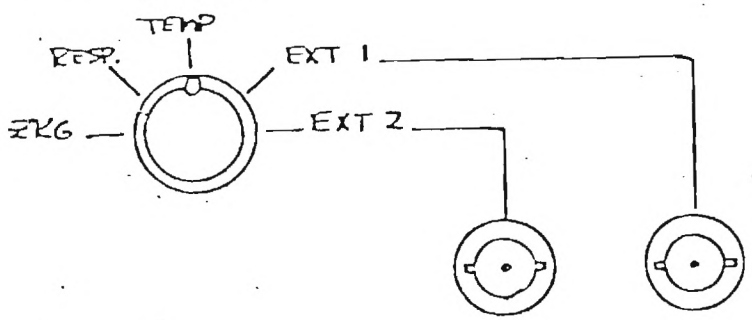


DISPLAY SELECT

X AXIS (secs/cm)



Y AXIS



APPENDIX II

POWER DENSITY MEASUREMENTS OF BIFOCAL LENS ANTENNA PERFORMED BY SPATIAL DYNAMICS

NOV 8 1982

SPATIAL DYNAMICS, LTD.
1924 BROADWAY — NUMBER 10
Basche-Sage Place
BAKER, OREGON 97814 (503) 523-6909

November 5, 1982

Intermedics
P O Box 617
Freeport, Texas 77541

Attention: Reese Terry

Dear Reese:

Please find enclosed the documentation for the P Band testing. The testing was done at three depth locations.

A. As close to the exit face as possible.
B. At the maximum power point of 1/8 wavelength from the exit face.
C. At the back of the tank.

Eighty-one individual measurements were made at each depth location in an 8"x8" matrix. The positioning apparatus to hold the measuring probe was fashioned from glass in readily available stock. Chloroform was chosen as the measuring media because:

1. It has a slower propagation velocity than the lens (a requirement for the lens to function).
2. It's dielectric constant is approximately equal to the tanks and positioning apparatus, thereby making them translucent.
3. The tanks electrically appear equal to or greater than ½ wavelength in any dimension.
4. Allows for use of readily available fish tanks.
5. Chloroform is readily available from our local hospital.

As you can see by studying the results, the energy does appear convergent 1/8 of a wavelength from the exit face of the lens in either direction. This satisfies me that this lens operates exactly as our 487 MHz system which was tested in identical fashion. The dotted lines on the power measurements charts connect like power readings.

Data from these tests is available to you should you desire.

Sincerely,

Tex Yukl

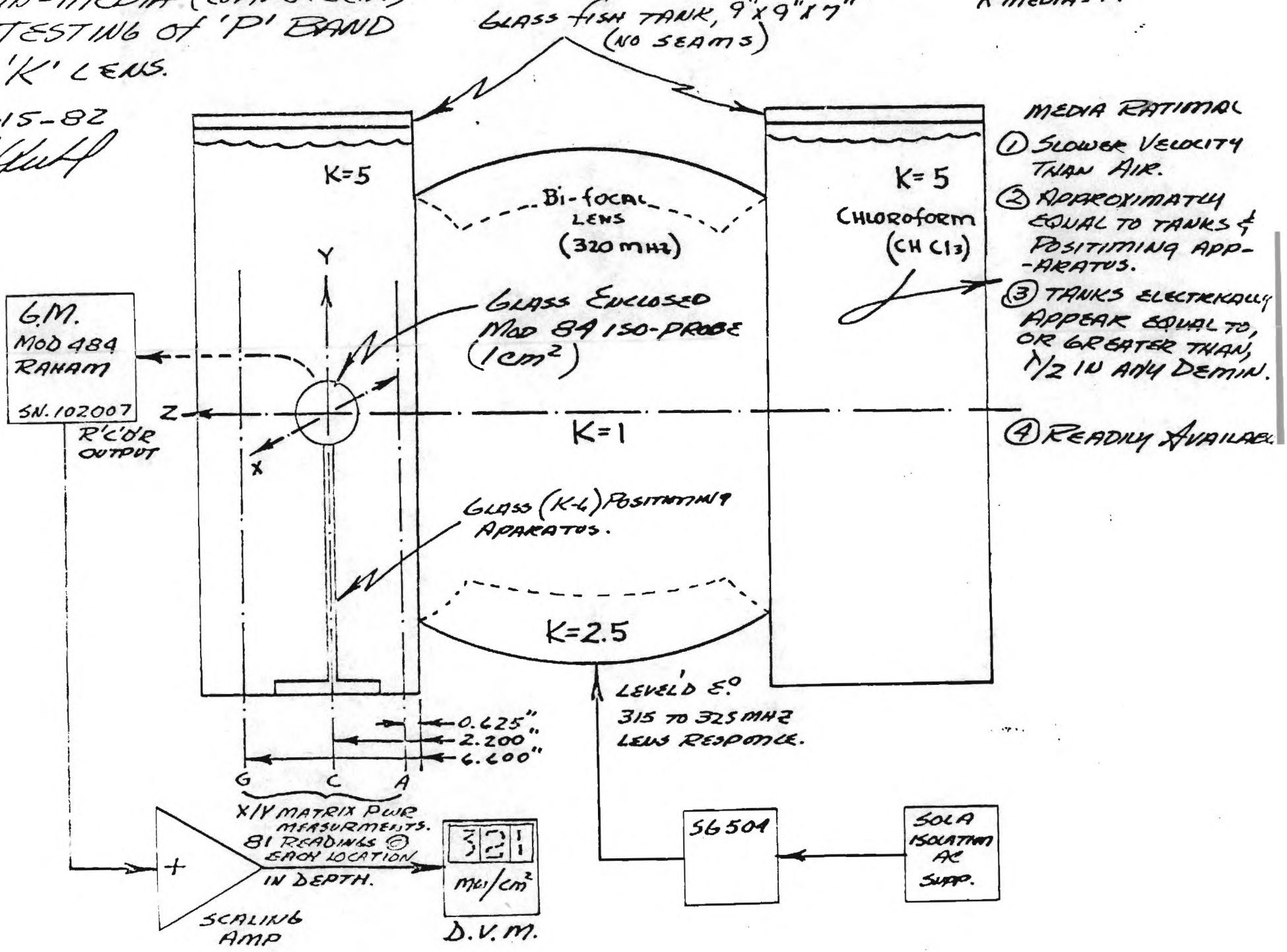
TY/vg

Enclosures

BASIC SET-UP FOR
IN-MEDIA (CONVERGENT)
TESTING OF 'P' BAND
'K' LENS.

10-15-82
J. Guth

TEMP = 25°C
λ AIR = 37"
λ MEDIA = 17"



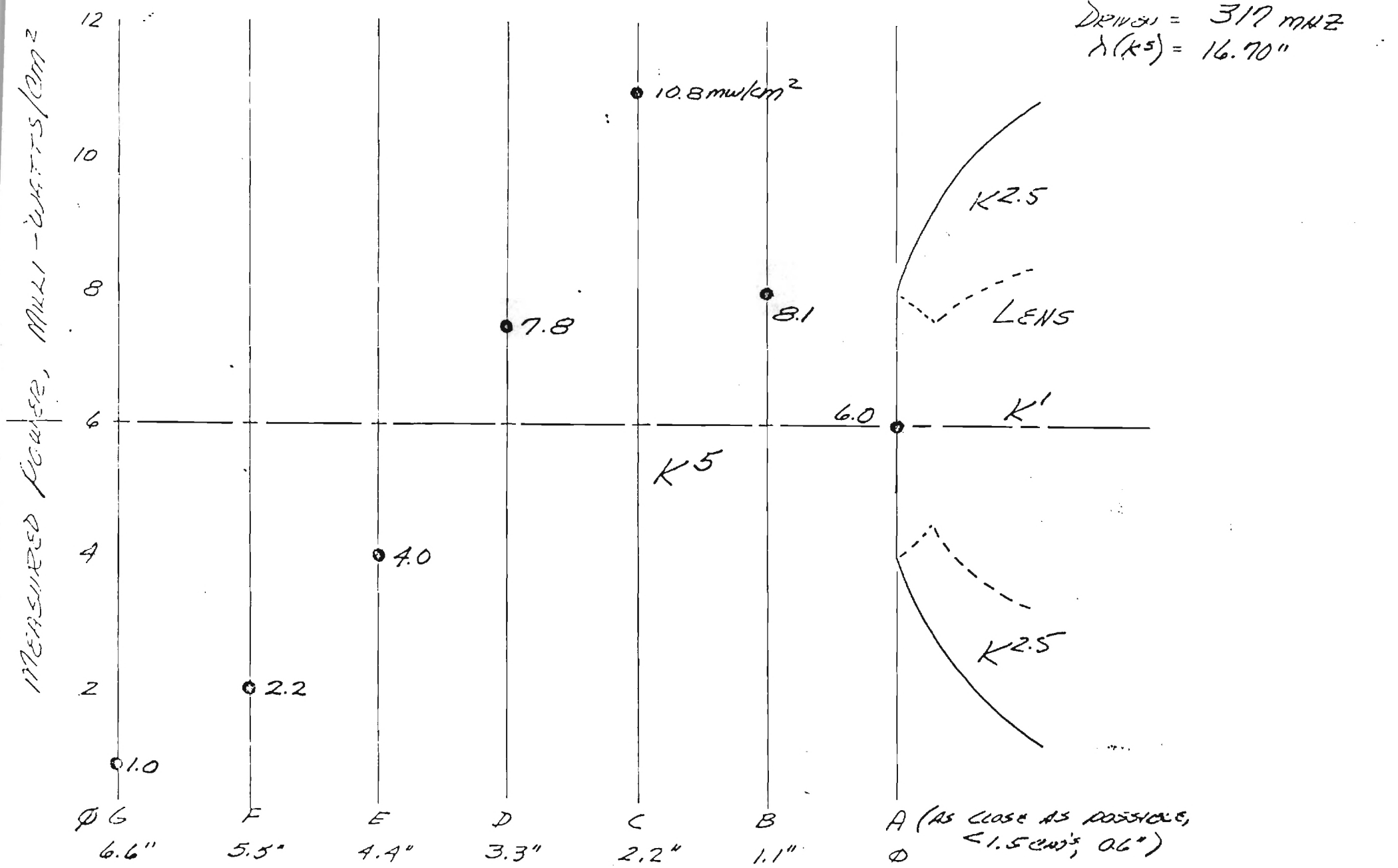
MEDIA RATIONAL

① SLOWER VELOCITY THAN AIR.

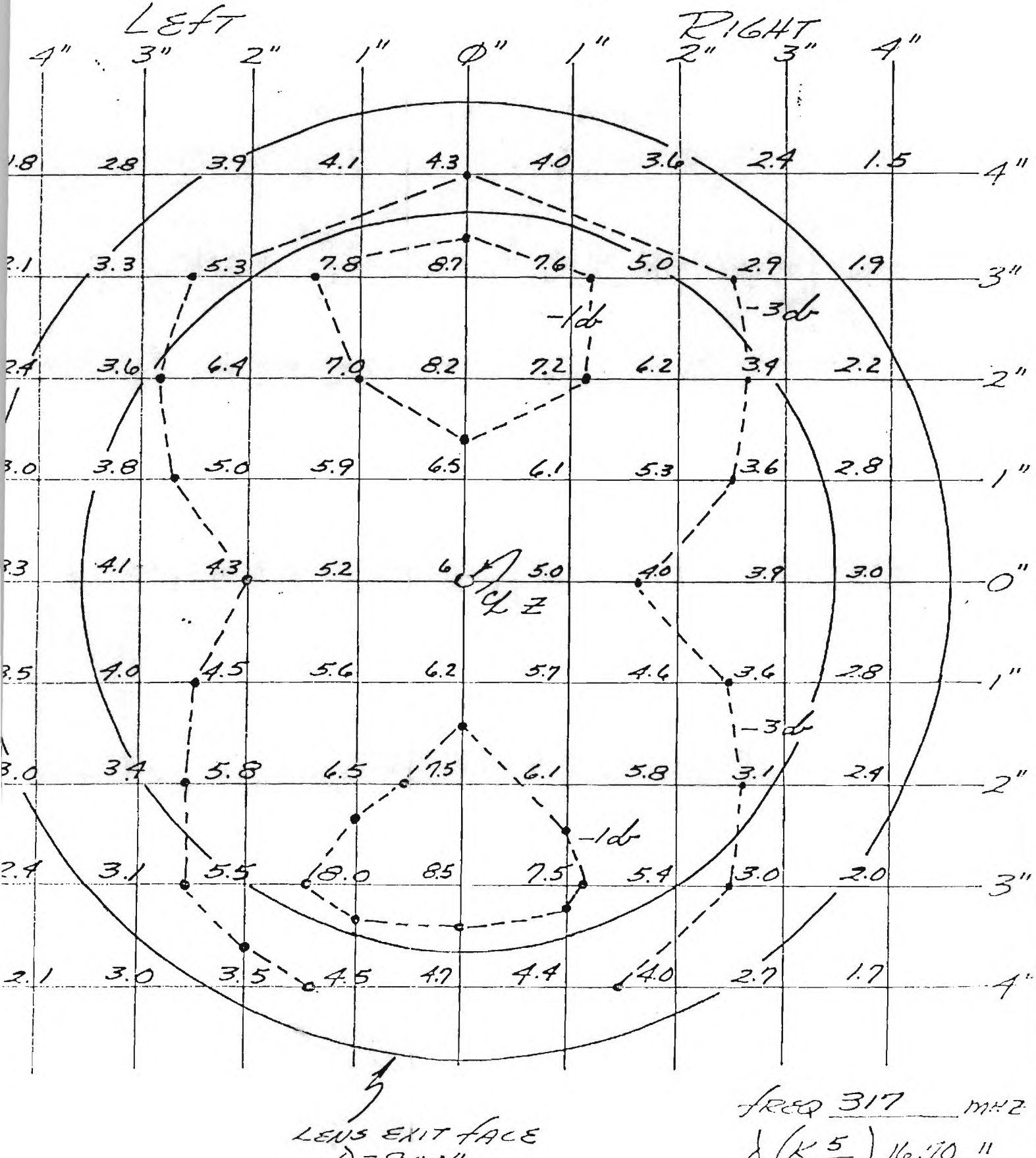
② APPROXIMATELY EQUAL TO TANKS & POSITIONING APP--ARATUS.

③ TANKS ELECTRICALLY APPEAR EQUAL TO, OR GREATER THAN, λ/2 IN ANY DEMIN.

④ READILY AVAILABLE


Driven = 317 mHz
λ(K5) = 16.70"
INTENSITIZED FIELDS, MILLI-WATTS/(cm)²
12
10
8
6
4
2
10.8 mw/cm²
7.8
8.1
4.0
2.2
1.0
6.0
K5
K'
K2.5
LENS
K2.5
Ø
G
F
E
D
C
B
A (AS CLOSE AS POSSIBLE, <1.5 cm's; 0.6")
6.6"
5.5"
4.4"
3.3"
2.2"
1.1"
Ø

X & Y LEVELS AT DEPTH A (MILLI-WATTS / CM²)

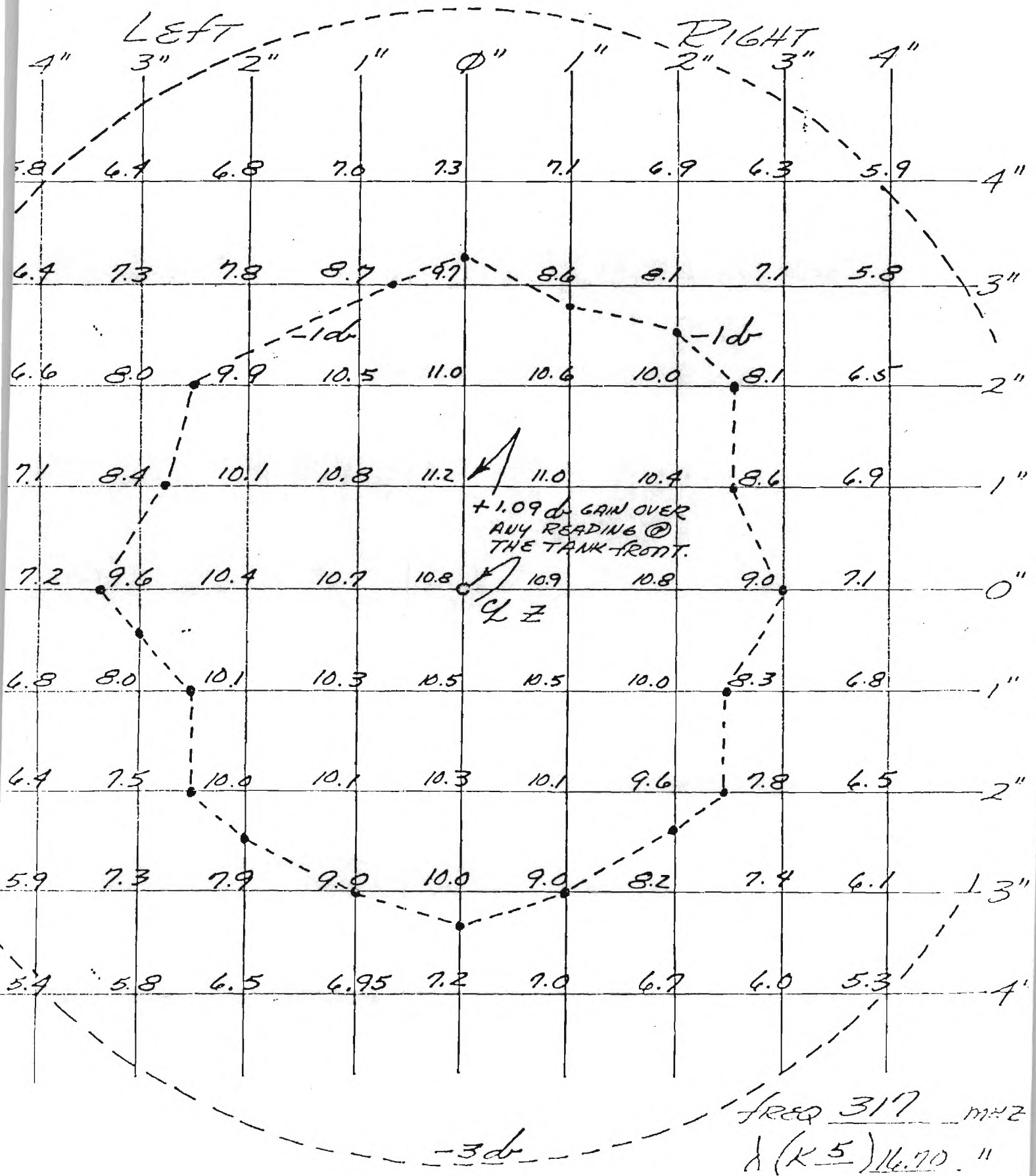


LENS EXIT FACE
D = 9.00"

FREQ 317 MHZ

λ (K 5) 16.70 "

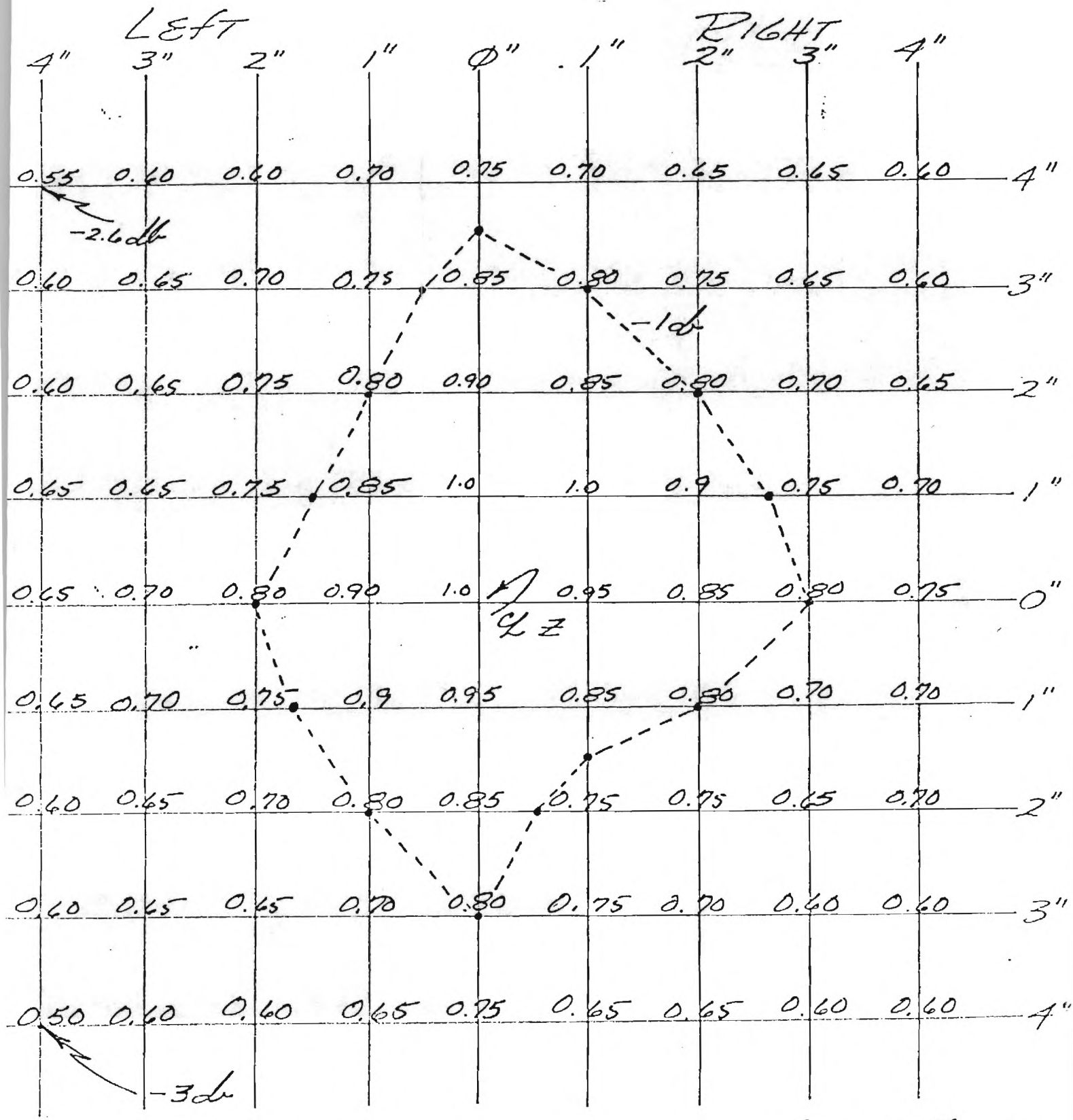
X & Y LEVELS AT DEPTH C (MILLI-WATTS / CM²)



FREQ 317 MHZ

λ (K 5) 16.70 "

X & Y LEVELS AT DEPTH 6 (MILLI-WATTS / CM²)



ALL DATA WAS ROUNDED TO 2ND DECIMEL PT BY D.V.M.

FREQ 317 MHZ

λ (K5) 16.70"